UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

PC Code: 105501
DP Barcode: D414217

MEMORANDUM

DATE: May 20, 2014

SUBJECT: Transmittal of the Draft Environmental Fate and Ecological Risk Assessment in Support of the Registration Review of Tebuthiuron

TO: Joel Wolf, Chemical Review Manager
Risk Management and Implementation Branch IV
Pesticide Re-evaluation Division
7508P

FROM: Ibrahim Abdel-Saheb, Ph.D., Environmental Scientist (For IAS) 5-20-14
Steve Carey, Biologist 5/20/14
Environmental Risk Branch 6
Environmental Fate and Effects Division
7507P

THROUGH: Mark Corbin, Branch Chief
Environmental Risk Branch 6
Environmental Fate and Effects Division 5-20-14
7507P

The Environmental Fate and Effects Division (EFED) has completed the preliminary ecological risk, environmental fate, endangered species, and drinking water assessments conducted in support of the Registration Review of the herbicide Tebuthiuron (PC Code 105501).

Risk Conclusions

The results of this screening-level risk assessment indicate that the current uses of tebuthiuron may potentially cause direct adverse effects to Federally-listed threatened and endangered (hereafter referred to as "listed") and non-listed mammals, terrestrial-phase amphibians, reptiles, small-sized birds on an acute exposure basis. Chronic risk to listed and non-listed birds, terrestrial-phase amphibians, reptiles, and mammals may also occur. Risk to listed and non-listed species of terrestrial plants and aquatic vascular and nonvascular plants may occur. Whereas for terrestrial invertebrates, available lines of evidence indicate that the potential for risk is low. Tebuthiuron is not expected to adversely affect aquatic vertebrates and invertebrates. The risks may extend to indirect effects upon listed species that depend upon that taxonomic group as a resource.

At this current stage of the registration review process, it is premature to make direct or indirect effects determinations until further refinements are conducted. An in-depth listed species evaluation determining the potential co-occurrence of listed species and use patterns of tebuthiuron is needed; however, additional information on the biology of listed species, the locations of these species, and the locations of use sites are needed to determine the extent to which screening assumptions regarding an action area apply to a particular listed organism.

Tables 1 and 2 summarize the maximum uses assessed and the taxa that may potentially be directly at risk from exposure to tebuthiuron as a result of broadcast spray and granular applications, respectively. **Table 3** summarizes the area percentage of spot treatment uses needed to exceed the listed species LOC from spraying or with granules/pellets/tablets using ground-based equipments.

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Table 1. Risk to Taxon Resulting from Tebuthiuron Use Patterns Sprayed at Maximum Single Application Rate of 6 lb a.i./A					
Use Pattern Category	**Aquatic Organisms (surrogate for aquatic-phase amphibians)**	**Birds, (surrogate for terrestrial-phase amphibians and reptiles)**	**Mammals**	**Plants[1]**	**Terrestrial Invertebrates**
Rangeland and Pastures	Acute risk: Not expected. Highest RQ = 0.02 Chronic risk: Not expected Highest RQ = 0.2	Acute risk: Expected for small-sized birds consuming tebuthiuron directly. Highest RQ=0.98, up to 10x the listed LOC of 0.1; however, extremely low food consumption of the test material was observed in passerines. No effect for medium- and large-sized birds. Days of exceedance for acute risk to birds using maximum scenario = 115 days. Application rate needed to not exceed the listed species LOC = 0.25 lb a.i./A. Chronic risk: Expected for birds. Highest RQ = 14, exceeds 14x the listed LOC of 1. Days of exceedance for chronic risk to birds using maximum scenario = 140 days. Application rate needed to not exceed the listed species LOC = 0.4 lb a.i./A. Distance of risk to non-target birds downwind (drift only) from edge of field: Up to 139 feet with aerial applications; up to 38 feet with ground applications.	Acute risk: Expected for all sizes of mammals. Highest RQ=1.6, exceeds 16x the listed LOC of 0.1. Days of exceedance for acute risk to mammals using maximum scenario = 60 days. Application rate needed to not exceed the listed species LOC = 0.15 lb a.i./A. Chronic risk: Expected for mammals. Highest RQ=45, exceeds 45x the listed LOC of 1. Days of exceedance for chronic risk to mammals using maximum scenario = 100 days. Application rate needed to not exceed the listed species LOC = 0.15 lb a.i./A. Distance of risk to non-target mammals downwind (drift only) from edge of field: up to 479 feet (aerial app.); up to 125 feet (ground app.).	Terrestrial and Aquatic: Risk to plants is expected. Highest RQ for listed terrestrial plants = 188 (dry area), 1031 (semi-aquatic area), and 94 (drift). Highest RQ for listed aquatic plants = 22 (vascular) and 55 (alga/diatoms). Application rate needed to not exceed listed LOC from runoff and/or drift: Terrestrial = 0.03 lb a.i./A (dry area), 0.005 lb a.i./A (semi-aquatic area), and 0.06 lb a.i./A (drift only). Aquatic = 0.27 lb a.i./A (vascular) and 0.11 lb a.i./A (alga/diatoms) Distance of risk to listed plant species downwind (drift only) from edge of field using maximum scenario: Terrestrial, up to and extends more than 997 feet; Aquatic nonvascular, up to 10 feet; and Aquatic vascular, None, runoff is main route of exposure to aquatic plants.	Non-listed and Listed: Uncertain; low likelihood of risk.

[1] Results are from aerial-based applications at which exposure is at its highest.

Table 2. Risk to Taxon Resulting from Tebuthiuron Use Patterns Applied as Granules at Maximum Single Application Rate of 6 lb a.i./A					
Use Pattern Category	**Aquatic Organisms (surrogate for aquatic-phase amphibians)**	**Birds, (surrogate for terrestrial-phase amphibians and reptiles)**	**Mammals**	**Plants[1]**	**Terrestrial Invertebrates**
Rangeland and Pastures	<u>Acute risk:</u> Not expected. Highest RQ = 0.02	<u>Acute risk</u>: Expected for small-sized birds that consume tebuthiuron-treated granules as their only source of food; however, low food consumption and regurgitation of the active ingredient were observed in the passerine bird studies. Granular RQs not available, assumed to be equivalent to spray RQs; however, some uncertainty exists since granular and pelleted formulations do not contain 100% of the active ingredient. No effect for medium- and large-sized birds.	<u>Acute risk</u>: Expected for small- and medium-sized mammals that consumes tebuthiuron-treated granules directly. Highest RQ=1.96, exceeds up to 20x the listed LOC of 0.1. Not expected for large-sized mammals; highest RQ = 0.08 Application rate needed to not exceed the listed species LOC for pelleted (40% a.i.) formulations = 0.3 lb a.i./A. Application rate needed to not exceed the listed species LOC for granular (5% a.i.) formulations = 2.5 lb a.i./A	<u>Terrestrial and Aquatic:</u> Expected for plants inhabiting areas adjacent to a site treated with granules containing 100% tebuthiuron. Highest RQ for listed terrestrial plants = 94 (dry area) and 938 (semi-aquatic area). Highest RQ for listed aquatic plants = 20 (vascular) and 26 (alga/diatoms). <u>Application rate needed to not exceed listed LOC from runoff:</u> Terrestrial = 0.06 lb a.i./A (dry area) and 0.006 lb a.i./A (semi-aquatic area). Aquatic = 0.3 lb a.i./A (vascular) and 0.23 lb a.i./A (alga/diatoms)	<u>Non-listed and Listed:</u> Uncertain; low likelihood of risk.

[1] Results are from the maximum application rate of 6 lb a.i./A at which exposure is at its highest

Table 3. Area Percentage of Spot Treatment Needed to Exceed the Listed Species LOC				
Taxa	**Application rates (lb a.i./A)**	**RQs assuming 100% area treated (highest to lowest)***	**Listed Species LOC**	**Area Percentage of application needed to exceed LOC[1]**
Birds (acute effects, liquid spray, broadcast)	6	**0.98**	Acute = 0.1	10%
	4	**0.66**		15%
Mammals (acute effects, liquid spray, broadcast)	6	**1.6**		6%
	4	**1.1**		9%
Mammals (acute effects, pellets, broadcast)	6	**1.96**		5%
	4	**1.31**		8%
Mammals (acute effects, granules, broadcast)	6	**0.24**		42%
	4	**0.16**		63%
Birds (chronic effects, broadcast, dietary-based)	6	**14**	Chronic = 1.0	7%
	4	**10**		10%
Mammals (chronic effects, liquid spray, broadcast, dietary-based)	6	**7**		14%
	4	**5**		20%
Mammals (chronic effects, broadcast, liquid spray, dose-based)	6	**45**		2%
	4	**30**		3%
Terrestrial Plants (listed effects, liquid spray, ground, broadcast)	6	**956**	Listed plants = 1.0	0.1%
	4	**638**		0.2%
Terrestrial Plants (listed effects, granules, ground, broadcast)	6	**938**		0.1%
	4	**625**		0.2%
Aquatic vascular plants (listed effects, liquid spray, ground, broadcast)	6	**20**		5%
	4	**14**		7%
	6	**26**		4%

Table 3. Area Percentage of Spot Treatment Needed to Exceed the Listed Species LOC

Taxa	Application rates (lb a.i./A)	RQs assuming 100% area treated (highest to lowest)*	Listed Species LOC	Area Percentage of application needed to exceed LOC[1]
Aquatic nonvascular plants (listed effects, liquid spray, ground, broadcast)	4	**18**		6%
Aquatic vascular plants (listed effects, granules, ground, broadcast)	6	**20**		5%
	4	**13**		8%
Aquatic nonvascular plants (listed effects, granules, ground, broadcast)	6	**26**		4%
	4	**17**		6%

*Bold values indicate LOC exceedance

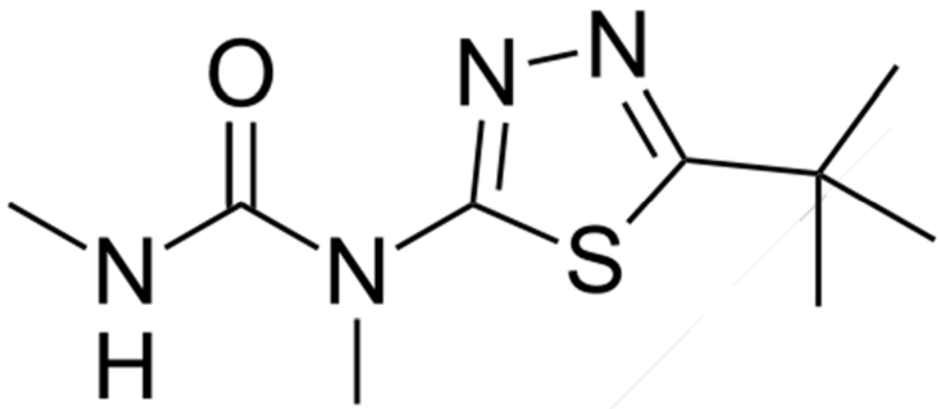
1 The threshold percentage is assessed to determine how much percent of exposure that RQ needs to exceed the LOC. For example, the highest acute RQ for birds inhabiting a field treated at 6 lb a.i./A is 0.98, which is up to 10x the listed species LOC of 0.1; to assess the % of exposure needed at which the LOC exceedance occurred, results indicate 10% is needed for the RQ to exceed the LOC. A “no effect” or “may affect” determination was not made since it is unknown what % of an actual area is typical spot treatment.

Basic Uncertainties

Application dates were chosen in accordance with the product label: “For optimum results, applications should be made prior to the resumption of active seasonal growth in the spring or before expected seasonal rainfall.” This can occur through a broad portion of a crop year and applications can therefore occur over a broad range of time. This creates uncertainty as to when to assign the application date for aquatic exposure modeling. Additional information regarding tebuthiuron usage, specifically concerning the timing of applications and geographical limitations of use, is of high value to EFED.

Office of Chemical Safety
and Pollution Prevention

Environmental Fate and Ecological Risk Assessment for the Registration of Tebuthiuron



Tebuthiuron
1-(*5-tert-butyl-1*,3,4-thiadiazol-2-yl)-1,3-dimethylurea
CAS Registry Number 34014-18-1
PC Code 105501

Prepared by:
Ibrahim Abdel-Saheb, Ph.D., Environmental Scientist
Steve Carey, Biologist

Reviewed by:
Amy Blankinship, Senior Scientist, ERB VI
William P. Eckel, Ph.D, Senior Science Advisor, ERB VI
Mark Corbin, Branch Chief, ERB VI

U. S. Environmental Protection Agency
Office of Pesticide Programs
Environmental Fate and Effects Division
Environmental Risk Branch VI
1200 Pennsylvania Ave., NW
Mail Code 7507P
Washington DC 20460

May 20, 2014

Table of Contents

1. Executive Summary

EFED has completed the Registration Review draft ecological risk assessment for Tebuthiuron (1-(*5-tert-butyl-1*, 3,4-thiadiazol-2-yl)-1 ,3-dimethylurea; CAS#: 34014-18-1; PC Code: 105501) and its end-use products. Tebuthiuron is a systemic, relatively nonselective herbicide, which is absorbed into the plant roots and is then translocated into other plant tissues. Once absorbed by the roots and translocated into the plant, it acts by inhibiting photosynthesis.

Tebuthiuron is used to control broadleaf and woody weeds, grasses and brush on feed crop sites (pasture and rangeland) and a variety of non-food crop sites including airports/landing fields, outdoor industrial areas, non-agricultural rights-of-way, fencerows, hedgerows, uncultivated areas/soils, and under paved roads and sidewalks in areas where no future landscaping is planned. Primary uses include rangeland and near railroads and other industrial facilities. Single active ingredient formulations include granular, pelleted/tableted, wettable powder, water dispersible granules, and technical grade/solid products. Four multiple active ingredient formulations (granules) also are registered. All formulations may be applied as broadcast, banded or spot treatments using ground equipment. The pelleted/tableted formulations also may be applied using aerial equipment.

The currently registered yearly single application rate of tebuthiuron is 6 lb a.i./A for the use on rangeland.

Tebuthiuron is persistent, mobile and can leach to ground water. It is resistant to biological and chemical degradation, and its principal route of dissipation in the environment appears to be leaching and/or runoff. Transport to ground water through leaching and to surface water through runoff are likely as a result of tebuthiuron's environmental persistence and low sorption to soil. Tebuthiuron has been detected in ground water in Texas and California. Considering its low Henry's Law constant (7.58×10^{-11} atm-m3/mol; at 25°C), the potential for vapor phase and long-range transport is not important.

With the exception of the pink shrimp, an estuarine/marine invertebrate, a small number of available data indicates tebuthiuron is practically non-toxic to freshwater and estuarine/marine fish and invertebrates on an acute exposure basis. On a chronic exposure basis, tebuthiuron resulted in decreased survival, reproduction (number of young/female), and growth (length) in these aquatic organisms.

On an acute exposure basis, tebuthiuron is slightly toxic to passerines, practically nontoxic to upland game birds and waterfowls and moderately toxic to mammals. Significant treatment-related reductions in eggs laid per pen, 14-day hatchling per number hatched, hatchling body weight, 14-day survivor weight, female and male weight gains, and eggshell thickness were determined from the chronic avian reproduction studies, while significant reductions in body weight and body weight gains were determined from the chronic mammalian reproduction study.

Available studies with beneficial insects (*i.e.*, honey bees) recorded no effects (*i.e.*, the no-effect level was greater than the highest concentration tested). As expected for an herbicide, the available plant toxicity data showed tebuthiuron to be toxic to aquatic and terrestrial plants based on reduced growth.

Risks are anticipated for terrestrial vertebrates that directly consume vegetation and granules treated with tebuthiuron on a daily basis. Exceedances of the listed species LOC were up to 10x for birds and up to 20x for mammals. The highest chronic RQs were approximately 14x and 45x the chronic LOC for birds and mammals, respectively. For spot treatment uses using sprayers, T-REX modeling indicates a field applied at the maximum application rate and with an assumption that 100% of the field is treated; an area percentage (threshold) of less than 10% and 5% of the field treated is needed to not exceed the listed species LOC for birds and mammals, respectively, consuming tebuthiuron-treated vegetation. Of the same scenario above, an area percentage of less than 7% and 2% is needed to not exceed the chronic LOC for birds and mammals, respectively. For granule uses, applying less than 42% of the field at the maximum rate would not exceed the listed species LOC for mammals.

Tebuthiuron is an herbicide; listed plant LOC exceedances for broadcast spraying and granular uses were expected. RQs were as high as 1031 for terrestrial plants and 55 for aquatic plants; and as high as 938 and 26 for terrestrial and aquatic plants, respectively, when granules are used.

No risks are expected for fish and aquatic invertebrates. Risks to terrestrial invertebrates are unlikely.

Identified potential risks to listed species are summarized in **Table 1.1** and detailed in **Table 5.1.**

Table 1.1. Potential Effects to Federally-Listed Taxa Associated with Direct Effects from the Registered Uses of Tebuthiuron.

Listed Plant Taxon	Potential Direct Effects	
Terrestrial and semi-aquatic plants – monocots and dicots	Yes*	
Aquatic nonvascular plants	Yes*	
Aquatic vascular plants	Yes*	
Listed Animal Taxon	**Potential Direct Effects**	
	Acute	**Chronic**
Terrestrial invertebrates	Uncertain[1]	N/A[2]
Mammals	Yes*	Yes*
Birds	Yes* for small-sized classes; No effect for mid- and large-sized classes	Yes* (all size classes)
Reptiles[3]	Yes*	Yes*
Terrestrial-phase amphibians[3]	Yes*	Yes*
Freshwater fish	No Effect	No Effect
Aquatic-phase amphibians[4]	No Effect	No Effect
Freshwater invertebrates	No Effect	No Effect
Estuarine/marine fish	No Effect	No Effect
Estuarine/marine invertebrates	No Effect	No Effect

* At this current stage of the Registration Review process, it is premature to make effects determinations until further refinements are conducted.
[1] Although no effects were seen in the acute contact toxicity test with honey bees at the max dose (100 µg a.i./bee), public data suggest individual terrestrial invertebrate taxonomic groups increased or decreased in population when exposed to tebuthiuron. Further, given that no endpoints were available, EFED cannot preclude effects to this taxon.
[2] No methodology available to measure chronic effects to terrestrial invertebrates.
[3] Birds are surrogates for reptiles and terrestrial-phase amphibians
[4] Fish are surrogates for aquatic phase amphibians.

Potential effects to federally-listed endangered and depth threatened species (listed species) based on LOC exceedances require an in-depth listed species evaluation determining the potential co-occurrence of listed species and use patterns of tebuthiuron.

Based on this screening-level assessment, acute and chronic risk resulting from direct effects is not expected for listed freshwater and estuarine/marine fish (surrogates for aquatic-phase amphibians), and freshwater and estuarine/marine invertebrates.

Precautionary labeling for beneficial insects is not required based on acute toxicity data for honeybees. Risk resulting from direct effects to listed terrestrial invertebrates is uncertain from the use of tebuthiuron on its registered use sites.

Potential direct effects on listed birds (surrogates for terrestrial-phase amphibians and reptiles), mammals, and terrestrial and aquatic plants from the use of tebuthiuron may be associated with modification of primary constituent elements (PCEs) of designated critical habitat, where such designations have been made. However, at this current stage of the Registration Review process, it is premature to make effects determinations for listed species until further scientific analysis and refinements are conducted, based on recommendations received from the National Academy of Sciences' (NAS) National Research Council (NRC) April 2013 report, available at http://www.nap.edu/catalog.php?record_id=18344. The NAS report outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that are compliant with the Endangered Species Act (ESA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The EPA along with the U.S. Fish & Wildlife Service (USFWS), the National Marine Fisheries Service (NMFS) (collectively, the Services), and the U.S. Department of Agriculture (USDA), released a summary of their implementation plan for assessing risks of pesticides to listed species ahead of the stakeholder workshop held on November 15, 2013. This plan was developed in response to the NAS' recommendations, including a common approach to risk assessment as a way of addressing scientific differences between EPA and the Services. During the workshop, the agencies received feedback from the public on the interim scientific approaches that were developed as part of the initial implementation of the NAS recommendations. These approaches will be jointly implemented and vetted as part of a phased iterative process. Once fully vetted, EPA will further refine the listed species effects determination portion of this risk assessment.

To make effects determinations for individual listed species, useful refinements may include, but are not limited to, analyses of: 1) more detailed, species-specific ecological and biological data; 2) more detailed and accurate information on tebuthiuron use patterns; and 3) sub-county level spatial proximity data for the co-occurrence of potential effects areas and listed species and any designated critical habitat. Examples of such refinements are described below.

EFED is currently developing tools that are expected to further refine the assessment and are designed to support effects determinations for individual federally listed species and their designated critical habitats (where applicable). Scientific information obtained from the Services, and other reliable sources is being collated by EFED to address all currently listed species. This information is being stored in an Office of Pesticide Programs (OPP) Pesticide Registration Information SysteM (PRISM) listed species knowledgebase. The listed species knowledgebase consists of an information repository that houses biological and behavioral information relevant to individual species (*e.g.*, habitat, diet, and life history, including specific temporal and spatial associations) and a document repository that contains supporting documents (*e.g*., USFWS recovery plans) and electronic information (*e.g*., GIS data files). For terrestrial taxa, biological information relevant to the assessment (*e.g*., diet and body weight) will be used to parameterize exposure estimates using a method consistent with currently used methods in the T-REX and T-HERPS models.

Refinements will also include more detailed analyses of the registered uses and specific use patterns that result in either "Likely to Adversely Affect" (LAA) or "Not Likely to Adversely Affect" (NLAA) determinations for federally listed species. The analyses may include more information on where, when, and how tebuthiuron is used on all use sites. Actual usage data (when available) and national land-cover datasets that indicate potential use sites [*e.g.*, National Land Cover Dataset (NLCD), Cropland Data Layer (CDL)] may be used to support a more refined analysis of where tebuthiuron is reasonably expected to be used. Similarly, refinements on the timing of applications and a more in-depth exploration of agronomic practices for tebuthiuron may be included as part of the refinement.

The refinements based on individual species data; additional, detailed usage information, when available; and recommendations from the NRC report are expected to help to more accurately identify potential areas of effect and to better inform effects and habitat determinations for listed species and any designated critical habitats.

Uncertainties

The conclusions of this risk assessment are limited by uncertainties concerning both exposure and toxicity.

Degradate 104 (N-[5-(1,14-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea) has the highest concentrations detected. Additionally, degradate 104 was detected in a retrospective ground water monitoring study and was a major degradate in a terrestrial field dissipation study, accounting for up to 23% of the mass applied. The degradate 104 was also found in an aerobic soil metabolism and soil photolysis studies comprising close to l7% of the mass applied. Degradate 104 was identified by the Health Effects Division (HED) as the only environmental fate degradate of tebuthiuron of toxicological concern to human health. The lack of data regarding maximum occurrence, mobility, and toxicity of degradate 104 are further uncertainties which are addressed through a total toxic residues approach.

2. Problem Formulation

2.1. Nature of Regulatory Action

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), all pesticides distributed or sold in the United States must be registered by the United States Environmental Protection Agency (EPA or the Agency). To determine whether a pesticide can be registered, the EPA evaluates the product's safety to non-target species based on a wide range of environmental and health effects studies. In 1996, FIFRA was amended by the Food Quality Protection Act (FQPA), and EPA was mandated to implement a new program for the periodic review of pesticides, *i.e.*, Registration Review[1]. The registration review program is intended to ensure that as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health and the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as changes occur, products in the marketplace can be used safely.

Additionally, potential effects to Federally listed endangered and threatened species (hereafter referred to as "listed") and their designated critical habitat are also considered under the Endangered Species Act (ESA) in order to ensure that the continued registration of tebuthiuron is not likely to jeopardize the continued existence of listed species or adversely modify their critical habitat. In order to meet the requirements of FIFRA and the ESA, this assessment follows EPA guidance on conducting ecological risk assessments (USEPA, 1998) and Office of Pesticide Program's Overview Document, which contains guidance for assessing pesticide risks to non-listed and listed species (USEPA, 2004).

Recent tebuthiuron ecological risk assessment- related documents performed by EFED include Tier II Aquatic Exposure Assessment for Selected Tebuthiuron Uses on Rangeland, Pastureland, and Other Non-Crop Lands in the Pacific Northwest: Endangered Species (ES) Consultation Package. Dated: July 12, 2004. DP Barcode D304225, and an initial Problem Formulation for Registration Review (2009, DP Barcode D363982).

2.2. Mode of Action

Tebuthiuron is a systemic, relatively nonselective herbicide which is absorbed into plant roots and is then translocated throughout the plant. It acts by inhibiting photosynthesis.

2.3. Use Characterization

[1] http://www.epa.gov/oppsrrd1/registration_review/

Single active ingredient formulations include granular, pelleted/tableted, wettable powder, water dispersible granules, and technical grade/solid products. Four multiple active ingredient formulations (granules) also are registered. All formulations may be applied as broadcast, banded or spot treatments using ground equipment. The pelleted/tableted formulations also may be applied using aerial equipment.

Labeled use patterns for tebuthiuron are summarized in **Table 2.1**, below.

Table 2.1. Tebuthiuron Uses by Label

Reg.No.	Formulation	% a.i.	Uses	# of apps/yr	Method of App.
013283-00018	Granular	2 6 (Diuron)	COMMERCIAL/INSTITUTIONAL/INDUSTRIAL PREMISES/EQUIPMENT (OUTDOOR)	2	Broadcast, No aerial app allowed
013283-00021	Granular	1 3 (Diuron)	COMMERCIAL/INSTITUTIONAL/INDUSTRIAL PREMISES/EQUIPMENT (OUTDOOR)	2	Broadcast, Application via shaker can
034913-00010	Granular	5	DRAINAGE SYSTEMS	1/3 yr, 1 time in 3 yr period up to 4 lbs a.i./A, no more than 6 lbs a.i./A per 2 consecutive treatments in any 6 year period	Broadcast, Band treatment, Spot treatment, , no aerial applications
034913-00015	Granular	1 3 (Diuron)	INDUSTRIAL AREAS (OUTDOOR), NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS, NONAGRICULTURAL UNCULTIVATED AREAS/SOILS, PAVED AREAS (PRIVATE ROADS/SIDEWALKS)	1/3 yr, 1 time in 3 yr period up to 4 lbs a.i./A, no more than 6 lbs a.i./A per 2 consecutive treatments in any 6 year period	Soil band treatment, Spot soil treatment, Soil broadcast treatment
034913-00016	Granular	2 6 (Diuron)	TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL	1/3 yr, 1 time in 3 yr period up to 4 lbs a.i./A, no more than 6 lbs a.i./A per 2 consecutive treatments in any 6 year period	Soil band treatment, Spot soil treatment, Soil broadcast treatment
062719-00107	Wettable powder	80	TERRESTRIAL NON-FOOD CROP; TERRESTRIAL FEED CROP	Max rate is 1-2 lb a.i./A, every 3 years for vulnerable sites; 1/3 yr, 1 time in 3 yr period up to 4 lbs a.i./A, no more than 6 lbs ai/A per 2 consecutive treatments in	Soil band treatment, Spot soil treatment, Soil broadcast treatment

				any 6 year period; spot treatment is allowed up to 6 lb a.i./A when needed	
062719-00121	Pelleted/ Tableted	20	TERRESTRIAL NON-FOOD CROP, TERRESTRIAL FEED CROP	Max rate is 1-2 lb a.i./A, every 3 years for vulnerable sites; 1/3 yr, 1 time in 3 yr period up to 4 lbs a.i./A, no more than 6 lbs a.i./A per 2 consecutive treatments in any 6 year period; spot treatment is allowed up to 6 lb a.i./A when needed	Soil band treatment, Spot soil treatment, Soil broadcast treatment
062719-00122	Pelleted/ Tableted	40	AQUATIC NON-FOOD INDUSTRIAL, TERRESTRIAL NON-FOOD CROP, TERRESTRIAL FEED CROP	Max rate is 1-2 lb a.i./A, every 3 years for vulnerable sites; 1/3 yr, 1 time in 3 yr period up to 4 lbs a.i./A, no more than 6 lbs a.i./A per 2 consecutive treatments in any 6 year period; spot treatment is allowed up to 6 lb a.i./A when needed	Soil band treatment, Spot soil treatment, Soil broadcast treatment
81927-37	Pelleted	80	TOTAL VEGETATION CONTROL IN NON-CROPLAND AND FOR WOODY PLANT CONTROL IN NON-CROPLAND, RANGELAND AND PERMANENT PASTURES.	Max rate is 1-2 lb a.i./A, every 3 years for vulnerable sites; 1/3 yr, 1 time in 3 yr period up to 4 lb a.i./A; spot treatment is allowed up to 6 lb a.i./A when needed	Surface applied, broadcast treatment, as a banded treatment, and aerial Application on rights-of-way is limited to helicopter only
81927-41	Pelleted	20		Max rate is 1-2 lb a.i./A, every 3 years for vulnerable sites; For all other areas, the maximum use rate and frequency of application is up to 4 lb a.i/acre once every three years, and no more than two treatments totaling 6 lb a.i./acre in any 6 year period, spot treatment is allowed up to 6 lb a.i./A when needed	

A screening level estimate of current usage of tebuthiuron is presented in **Table 2.2**. This screening level usage assessment presents usage data on an annual basis and is derived from

USDA's National Agricultural Statistics Service with data updated to 2013. This analysis amounts to 8,000 pounds of active ingredient used nationally on an annual basis with use on **Pastureland** being the dominant use pattern.

Table 2.2. Tebuthiuron Screening Level Usage Analysis (SLUA) for 2013

		Average	Percent Crop Treated	
	Crop	**Lbs. a.i.**	**Average**	**Maximum**
1	**Pastureland**	**8,000**	**<1**	**<2.5**

2.4. Conceptual Model

The potential terrestrial and aquatic exposure pathways and effects of the registered uses of tebuthiuron are shown in **Figures 1 and 2**. The conceptual model used to depict the potential ecological risk associated with the registered uses of tebuthiuron assumes that, as an herbicide, tebuthiuron is capable of adversely affecting terrestrial animals and plants including aquatic plants, provided that environmental concentrations are sufficiently elevated as a result of the labeled uses. Solid arrows in **Figures 1 and 2** depict the most likely routes of exposure and effects; dashed lines depict potential routes of exposure that are not considered likely for tebuthiuron.

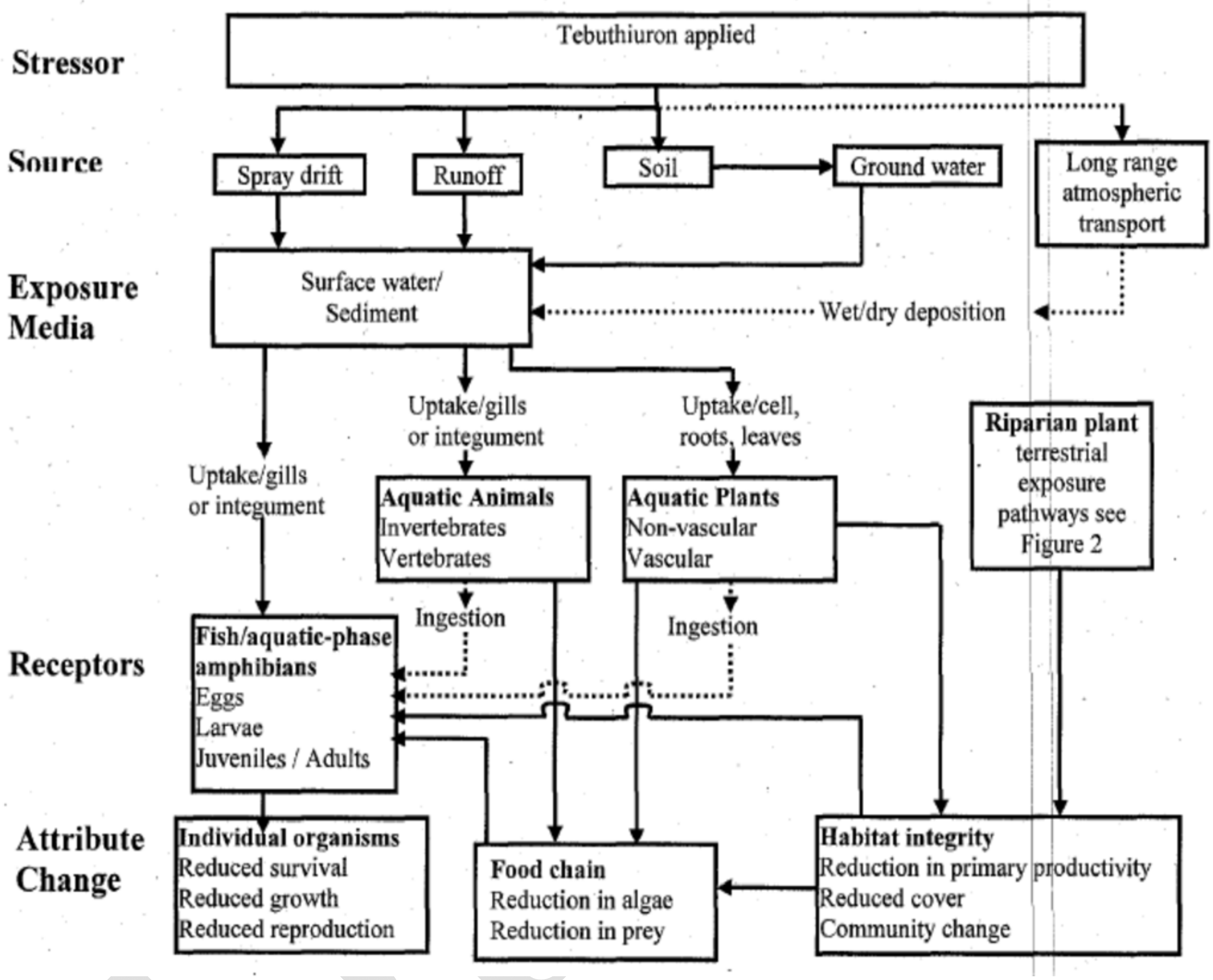


Figure 1. Conceptual Model of the Transport and Effects of Tebuthiuron for Aquatic Environments.
*Dotted lines indicate that, although this exposure route/media was considered, its contribution to the fate and transport of tebuthiuron is expected to be negligible

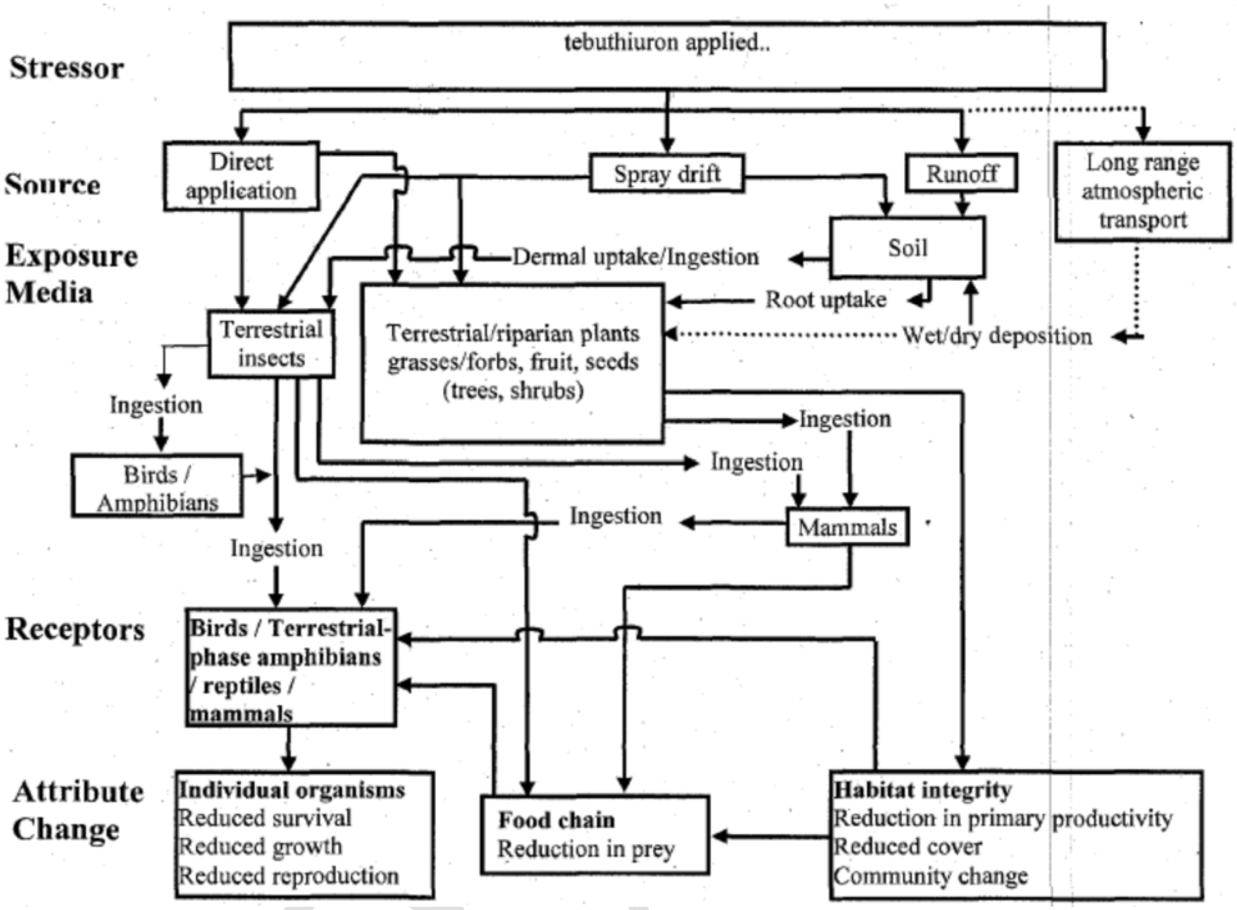


Figure 2. Conceptual Model of the Transport and Effects of Tebuthiuron for Terrestrial Environments.

*Dotted lines indicate that, although this exposure route/media was considered, its contribution to the fate and transport of tebuthiuron is expected to be negligible

The hypothesis for the risks of tebuthiuron to non-target animals focuses on both aquatic and terrestrial environments via potential exposure to the parent from direct spray, spray drift, and runoff. Leaching is considered a significant route of transport considering tebuthiuron is mobile in water. Dotted exposure routes are not likely (not anticipated to volatize). For terrestrial organisms, the major route of exposure is via diet, such as through consumption of plant leaves or insects, which contain tebuthiuron residues as a result of direct application and/or spray drift. For aquatic animal species, the major routes of exposure are direct contact via the respiratory surface (gills) or the integument. Aquatic vascular and non-vascular plants may also be exposed via direct uptake and adsorption. Risk to terrestrial plants is also considered in this screening-level assessment. In addition, tebuthiuron has a low potential for sorption to sediment; therefore, exposure to organisms that reside primarily in the benthos is not likely. Estimated exposure concentrations for all organisms are obtained through the use of several Agency exposure models.

The following risk hypothesis is presumed for this screening level assessment:

Based on the application methods, mode of action, direct toxicity to non-target aquatic and terrestrial species, the registered uses of tebuthiuron have the potential to reduce survival, reproduction, and/or growth in listed and non-listed terrestrial and aquatic animals and plants.

3. Analysis

3.1. Exposure Characterization

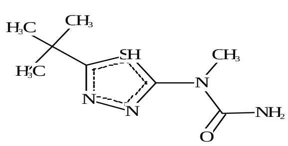
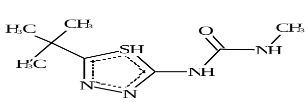
3.1.1. Environmental Fate and Transport Characterization

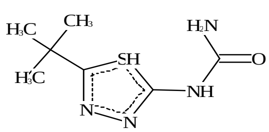
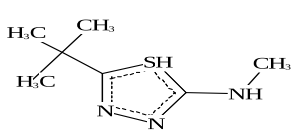
Tebuthiuron is persistent, mobile and can leach to ground water, as indicated by a small-scale retrospective ground water study (MRID 42390901). It is resistant to biological and chemical degradation, and its principle route of dissipation in the environment appears to be leaching and/or runoff. Transport to ground water through leaching and to surface water through runoff are likely as a result of tebuthiuron's environmental persistence and low sorption to soil. Because tebuthiuron has the potential to leach through the ground and because of the detections in Texas and California, the Agency is concerned about the potential for ground water contamination. Considering its low Henry's Law constant, (7.58 x 10^{-11} atm-m3/mol; at 25°C), the potential of vapor phase and long range transport is considered insignificant. The environmental fate study summaries are presented as Appendix A.

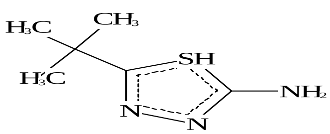
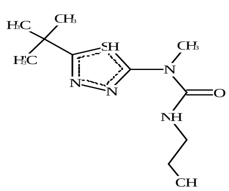
Based on available environmental fate laboratory studies, several minor degradates (< 10%) were identified (Table 3.1; Appendix B). Among these degradates, degradate 104 (N-[5-(1,14-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea) has the highest concentration detected. Additionally, degradate 104 was detected in a retrospective ground water monitoring study and was a major degradate in a terrestrial field dissipation study accounting for up to 23% of the mass applied. The degradate 104 was also found in an aerobic soil metabolism ($t_{1/2}$= 0.8 d) and soil photolysis ($t_{1/2}$= 18 d) studies (MRID # 41050201) comprising close to 7% of the mass applied. Degradate 104 was identified by the Health Effects Division (HED) as the only environmental fate degradate of tebuthiuron of toxicological concern to human health. A cumulative residue approach to model total tebuthiuron residues was applied for drinking water assessment purposes as well as in this ecological risk assessment.

In regards to the bioconcentration potential of tebuthiuron, a 28-day flow-through study in which bluegill sunfish were exposed to a nominal tebuthiuron concentration of 5.0 ppm resulted in bioconcentration factors of 1.98, 3.40, and 2.63 for edible tissue, non-edible tissue, and whole fish, respectively. Residues in the tissues consisted primarily of tebuthiuron and two metabolites (N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methyl-N' hydroxymethyl-urea [compound 109] and compound 103(OH) (hydroxylated form of parent tebuthiuron). Accumulated residues depurated rapidly from fish tissue with depuration half-lives of 0.33 and 0.51 days reported for edible and non-edible tissue, respectively (MRID 40819501). Due to the rapid depuration, bioaccumulation is not a concern.

Table 3.1. Tebuthiuron and Its Environmental Degradates.

Parent / Degradate Name and Structure	Percent of Applied		MRID #	Study Type
	Maximum	Day		
104: N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea	ND*	N/A**	N/A	hydrolysis
	ND	N/A	41305101	aqueous photolysis
	6.8	14	41050201	soil photolysis
	6.9	270	41328001	aerobic soil metabolism
	2.9	60	41328002	anaerobic soil metabolism
	1.5	21	41372501	aerobic aquatic metabolism
	ND	N/A	41913101	anaerobic aquatic metabolism
MolWt: 214.29 C8 H14 N4 O1 S1	ND	N/A	40768401	batch equilibrium
	N/A	N/A	N/A	laboratory volatility
	N/A	N/A	N/A	field volatility
	22.9	408	43318101	terrestrial field dissipation
	2.2 (edible)	21	40819501	bioaccumulation in fish
105: N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N=-methylurea	ND	N/A	N/A	hydrolysis
	ND	N/A	41305101	aqueous photolysis
	3.5	19	41050201	soil photolysis
	0.4	90	41328001	aerobic soil metabolism
	0.2	60	41328002	anaerobic soil metabolism
	0.4	28	41372501	aerobic aquatic metabolism
MolWt: 214.29 C8 H14 N4 O1 S1	ND	N/A	41913101	anaerobic aquatic metabolism
	ND	N/A	40768401	batch equilibrium

Parent / Degradate Name and Structure	Percent of Applied		MRID #	Study Type
	Maximum	Day		
	N/A	N/A	N/A	laboratory volatility
	N/A	N/A	N/A	field volatility
	ND	N/A	43318101	terrestrial field dissipation
	4.7 (edible)	21	40819501	bioaccumulation in fish
106: N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl] urea	ND	N/A	N/A	hydrolysis
	ND	N/A	41305101	aqueous photolysis
	2.7	5	41050201	soil photolysis
	ND	N/A	41328001	aerobic soil metabolism
	ND	N/A	41328002	anaerobic soil metabolism
	ND	N/A	41372501	aerobic aquatic metabolism
	ND	N/A	41913101	anaerobic aquatic metabolism
MolWt: 200.26 C7 H12 N4 O1 S1	ND	N/A	40768401	batch equilibrium
	N/A	N/A	N/A	laboratory volatility
	N/A	N/A	N/A	field volatility
	ND	N/A	43318101	terrestrial field dissipation
	ND	N/A	40819501	bioaccumulation in fish
107: 5-(1,1-Dimethylethyl)-2-methylamino-1,3,4-thiadiazole	ND	N/A	N/A	hydrolysis
	ND	N/A	41305101	aqueous photolysis
	ND	N/A	41050201	soil photolysis
	1.1	270	41328001	aerobic soil metabolism
	ND	N/A	41328002	anaerobic soil metabolism
	0.3	21	41372501	aerobic aquatic metabolism
MolWt: 171.26 C7 H13 N3 S1	ND	N/A	41913101	anaerobic aquatic metabolism
	ND	N/A	40768401	batch equilibrium
	N/A	N/A	N/A	laboratory volatility
	N/A	N/A	N/A	field volatility
	ND	N/A	43318101	terrestrial field dissipation
	ND	N/A	40819501	bioaccumulation in fish
108: 2-dimethylethyl-5-amino-1,3,4-thiadiazole	ND	N/A	N/A	hydrolysis
	ND	N/A	41305101	aqueous photolysis

Parent / Degradate Name and Structure	Percent of Applied		MRID #	Study Type
	Maximum	Day		
 MolWt: 157.23 C6 H11 N3 S1	ND	N/A	41050201	soil photolysis
	0.6	270	41328001	aerobic soil metabolism
	ND	N/A	41328002	anaerobic soil metabolism
	0.1	7	41372501	aerobic aquatic metabolism
	ND	N/A	41913101	anaerobic aquatic metabolism
	ND	N/A	40768401	batch equilibrium
	N/A	N/A	N/A	laboratory volatility
	N/A	N/A	N/A	field volatility
	ND	N/A	43318101	terrestrial field dissipation
	ND	N/A	40819501	bioaccumulation in fish
109: N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-hydroxymethyl-N-methylurea	ND	N/A	N/A	hydrolysis
	ND	N/A	41305101	aqueous photolysis
	ND	N/A	41050201	soil photolysis
 MolWt: 258.34 C10 H18 N4 O2 S1	ND	N/A	41328001	aerobic soil metabolism
	0.2	60	41328002	anaerobic soil metabolism
	0.3	7	41372501	aerobic aquatic metabolism
	ND	N/A	41913101	anaerobic aquatic metabolism
	ND	N/A	40768401	batch equilibrium
	N/A	N/A	N/A	laboratory volatility
	N/A	N/A	N/A	field volatility
	ND	N/A	43318101	terrestrial field dissipation
	40.1 (edible)	21	40819501	bioaccumulation in fish

*: Not determined.
**: Not applicable.

Table 3.2 lists the environmental fate properties of tebuthiuron in the submitted environmental fate and transport studies.

Table 3.2. Summary of tebuthiuron Environmental Fate Properties

Study/Parameter	Value (units)	MRID # Or Source	Study Status and Comments
Hydrolysis	Stable	Acc. No 00020779	Acceptable
Solubility	2500 (mg/L @ 25ºC)	Tomlin CDS, ed (2004-05)	N/A
Vapor Pressure	3.0×10^{-7} (torr)	Tomlin CDS, ed (2004-05)	N/A
log Kow	1.79 (estimation)	BioByte. 1995. ClogP for Windows Program (v1.0). BioByte Corp., Claremont, CA.	N/A
Direct Aqueous Photolysis	Stable	41305101	Acceptable
Aerobic Soil Metabolism	$t_{1/2}$ = 1062 days	41328001	Acceptable
Anaerobic Soil Metabolism	Stable	41328002	Acceptable
Aerobic Aquatic Metabolism	683	41372501	Acceptable
Anaerobic Aquatic Metabolism	> 1 year	41913101	Acceptable
Kd-ads	0.11, 0.62, 0.82, and 1.82 mL/g	40768401	Acceptable
Terrestrial Field Dissipation	$t_{1/2}$ = 1-2 years	43318101	Acceptable
Fish Bioaccumulation	Bioconcentration factor BCF= 1.98, 3 .40, and 2.63 for edible tissue, non-edible tissue, and whole fish, respectively.	40819501	Acceptable

3.1.2. Measures of Aquatic Exposure

Aquatic exposures are quantitatively estimated for all assessed uses using scenarios that represent high exposure sites for tebuthiuron use. Each of these sites represents a 10-hectare field that drains into a 1-hectare pond that is 2 meters deep and has no outlet. Exposure estimates generated using the standard pond are intended to represent a wide variety of vulnerable water bodies that occur at the top of watersheds including prairie pot holes, playa lakes, wetlands, vernal pools, man-made and natural ponds, and intermittent and first-order streams. As a group, there are factors that make these water bodies more or less vulnerable than the standard surrogate pond. Static water bodies that have larger ratios of drainage area to water body volume would be expected to have higher peak EECs than the standard pond. These water bodies will be either shallower or have large drainage areas (or both). Shallow water bodies tend to have limited additional storage capacity, and thus, tend to overflow and carry pesticide in the discharge whereas the standard pond has no discharge. As watershed size increases beyond 10 hectares, at some point, it becomes unlikely that the entire watershed is planted to a single crop, which is all treated with the pesticide. Headwater streams can also have peak concentrations higher than the standard pond, but they tend to persist for only short periods of time and are then carried downstream.

Tebuthiuron environmental fate data used for generating model parameters are listed in **Table 3.3**. Chemical property input values were chosen in accordance with current input parameter guidance (USEPA, 2009[1]). Using meteorological files information associated with each PRZM scenario, application dates were chosen in according with the product label: "For optimum results, applications should be made prior to the resumption of active seasonal growth in the spring or before expected seasonal rainfall".

The maximum labeled single and annual application rate for tebuthiuron is at 6 lb a.i./A for broadcast applications via spray or granules. Only one application per year or every three years is assumed. However, a maximum application rate of 4 lb a.i./A is also expected for several of the same uses that is applied at 6 lb a.i./A. Thus, the application rate of 4 lb a.i./A was included in the assessment to evaluate whether the risk picture would improve significantly when the 6 lb a.i./A application rate is reduced to 4 lb a.i./A. The application methods assumed are as follows: aerial, ground, shaker can, spreader, hand held spray gun, backpack sprayer, and band sprayer. For this assessment, aerial and ground broadcast applications involve the highest application rates and are used to assess the potential risk to wildlife exposed to tebuthiuron. EECs for spot treatment applications are not available; however, exposure from spot treatment using backpack sprayers or granules will be subsequently discussed for any potential risks to non-target wildlife and plants after the assessment on broadcast applications as a liquid spray or with granules.

Table 3.3. Summary of PRZM/EXAMS Environmental Fate Data Used for Aquatic Exposure Inputs for Tebuthiuron

Fate Property	Value (unit)	MRID (or source)	Comment
Molecular Weight	228.3	Tomlin CDS, ed (2004-05)	
Henry's constant	1.2E-10 (atm-m^3/mol)	Tomlin CDS, ed (2004-05)	
Vapor Pressure	3.0E-7 (torr)	Tomlin CDS, ed (2004-05)	
Solubility in Water	2500 (mg/L)	Tomlin CDS, ed (2004-05)	
Application Rate	6.72 (kg a.i./ha) 4.48 (kg/ha)	EPA Reg No. 62719-122	
Number of Applications	1	EPA Reg No. 62719-122	
Interval between Applications (days)	Not applicable	EPA Reg No. 62719-122	
Photolysis in Water	Stable	MRID 41305101	
Aerobic Soil Metabolism Half-life	270.6 (day)	MRID 41328001	3X aerobic soil metabolism half-life for total residues (a single aerobic soil metabolism half-life value is available); input parameter per Input Parameter Guidance (1)

Fate Property	Value (unit)	MRID (or source)	Comment
Hydrolysis	Stable	Acc. No 00020779	
Aerobic Aquatic Metabolism (water column)	2050 (day)	MRID 41372501	3X aerobic aquatic metabolism half-life for total residues (a single aerobic aquatic metabolism half-life value is available); input parameter per Input Parameter Guidance (1)
Anaerobic Aquatic Metabolism (benthic)	Stable	MRID 41913101	
K_{oc}	85.2 (mg/L)	MRID 40768401	Binding is correlated to organic carbon content. Mean Koc; input parameter per Input Parameter Guidance (1)
Chemical Application Method (CAM)	2		pre-plant or pre-emergence, unincorporated

[1] Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides; Version 2.1, October 22, 2009.

Results from each PRZM scenario are presented in **Table 3.4.** Output that generates peak EECs are reported in **Appendix C**. A typical available grass PRZM scenario used as pasture is alfalfa.

Table 3.4. Tier II Concentrations of Tebuthiuron in Surface Water

Tier II PRZM/EXAMS Scenario		Application rate	
		6 lbs a.i./A	4 lbs a.i./A
		(ppb)	
TXalfalfaOP	Aerial	1109	736.3
	Ground	1018	679
	Granular	997.3	664.9
MNalfalfaOP	Aerial	558.6	372.7
	Ground	376	251
	Granular	330.8	220.8
NCalfalfaOP	Aerial	604	403
	Ground	453.1	301.5
	Granular	414.7	276.8
PAalfalfaOP	Aerial	693.9	462.9
	Ground	534.8	355.9
	Granular	494.8	329.9
CAalfalfa_WirrigOP	Aerial	498.9	332
	Ground	367.9	245
	Granular	335	223

Because of the persistence of this compound, the 1 in 10 year PRZM/EXAMS EECs are expected to represent 30 years of residue accumulation in the pond. This fact was presented by plotting time against the EECs from the following scenarios modeled: TXalfalfaOP (aerial), and

PAalfalfaOP (aerial) (ones with highest EECs) show a continuous accumulation of tebuthiuron in pond (**Appendix D**). Such residue accumulation is driven mostly by the persistence of the compound as well as by the lack of flow out of the pond. In cases where a flowing water exists, the EEC over the long run would not be as high.

3.1.3. Measures of Terrestrial Exposure

3.1.3.1. Terrestrial Animals

Exposure estimates for terrestrial animals assumed to be in the target area or in an area exposed to spray drift or granules are derived using the T-REX[2] model (version 1.5.2.). This model incorporates the Kenaga nomograph, as modified by Fletcher *et al.* (1994), which is based on a large set of actual field residue data. The upper limit values from the nomograph represent an approximation of the highest residue value observed in the data set (Hoerger and Kenaga 1972). Consideration is given to different types of feeding strategies for mammals and birds, including herbivores, insectivores and granivores. For dose-based exposures, three weight classes of birds (20, 100, and 1000 g) and mammals (15, 35, and 1000 g) are considered. A default foliar dissipation half-life of 35 days is used based on the work of Willis and McDowell (1987).

Ingestion of Food Items Based on Foliar Application

The same tebuthiuron application and seasonal rate limitations as evaluated in previous assessments (*i.e*., maximum broadcast application rates of 6.0 and 4.0 lb a.i. and one application per year) are taken from active labels and are used to estimate terrestrial exposure for this assessment. The dietary-based EECs on a variety of food items from the use of wettable powder and water dispersible granule formulations of tebuthiuron applied at the maximum label rate are provided in **Table 3.5**; dose-based EECs are provided in **Table 3.6**.

Table 3.5. T-REX Calculated Dietary-Based EECs of Tebuthiuron on Food Residues.

Application Rate (lb a.i./A)	Food Type	Maximum Dietary-based EECs (mg/kg-diet)
6.0	Short Grass	1440
	Tall Grass	660
	Broadleaf plants	810
	Fruits/pods/seeds	90
	Arthropods	564
4.0	Short Grass	960
	Tall Grass	440
	Broadleaf plants	540
	Fruits/pods/seeds	60
	Arthropods	376

[2] USEPA. 2013. Pesticides: Science and Policy. Terrestrial Models, T-REX Version 1.5.2. http://www.epa.gov/oppefed1/models/terrestrial/

Table 3.6. T-REX Calculated Dose-Based EECs of Tebuthiuron on Food Residues.							
Application Rate (lb a.i./A)	Food Type	Dose-based EECs for Birds (mg/kg-bw)			Dose-based EECs for Mammals (mg/kg-bw)		
		Small (20 g)	Medium (100 g)	Large (1000 g)	Small (15 g)	Medium (35 g)	Large (1000 g)
6.0	Short grass	1640	935	419	1373	949	220
	Tall grass	752	429	192	629	435	101
	Broadleaf plants	922	526	236	772	534	124
	Fruits/pods	103	58	26	86	59	14
	Arthropods	642	366	164	538	372	86
	Seeds (granivore)	23	13	6	19	13	3
4.0	Short grass	1093	623	279	915	633	147
	Tall grass	501	286	128	420	290	67
	Broadleaf plants	615	351	157	515	356	83
	Fruits/pods	68	39	17	57	40	9
	Arthropods	428	244	109	358	248	57
	Seeds (granivore)	15	9	4	13	9	2

Ingestion of granules based on broadcast applications

T-REX includes the capability to calculate the LD_{50}/ft^2 risk index values for granular applications. Conceptually, an LD_{50}/ft^2 is the amount of a pesticide estimated to kill 50% of exposed animals in each square foot of applied area. Although a square foot does not have defined ecological relevance, and any unit area could be used, risk presumably increases as the LD_{50}/ft^2 value increases. For additional information on the LD_{50}/ft^2 risk index, please refer to USEPA (1992). The LD_{50}/ft^2 value is calculated using a toxicity value (adjusted LD_{50}) and the EEC (mg a.i./ft^2) and is directly compared with the Agency's levels-of-concern (LOCs). In addition, pellets and granules are considered equivalent.

Assuming a maximum of 40% active ingredient in pelleted/tableted formulations, the EEC for tebuthiuron-treated pelleted/tableted formulations applied at the maximum label rate of 6 and 4 lb a.i./A is 25 and 16.7 mg a.i./ft^2, respectively. For granular formulations which contains a maximum of 5% tebuthiuron, the EEC at 6 and 4 lb a.i./A is 3.12 and 2.08 mg a.i./ ft^2, respectively.

3.1.3.2. Terrestrial Plants

Tebuthiuron exposure to terrestrial and semi-aquatic plants is estimated using the TerrPlant[3] (version 1.2.2) model. The model generates EECs for plants residing near a use area that may be exposed via runoff and/or spray drift from foliar and granular applications. The EECs are generated from one application at the maximum rate for a particular use and compound-specific

[3] USEPA. 2013a. Pesticides: Science and Policy. Terrestrial Models, TerrPlant Version 1.2.2. http://www.epa.gov/oppefed1/models/terrestrial/

solubility information. Only a single application is considered because it is assumed that for plants, toxic effects are likely to manifest shortly after the initial exposure and that subsequent exposures do not contribute to the response. Hence, the model estimates EECs based on application rate, the solubility limit, and default assumptions of drift. The EECs for terrestrial and semi-aquatic plants for a single application of tebuthiuron at 6 and 4 lb a.i./A are presented in **Table 3.7**.

To characterize potential non-target plant exposure from spray drift alone, Tier 1 modules in AgDRIFT (v. 2.1.1) were used to estimate EECs for off-site spray drift exposure in dry and semi-aquatic areas and water bodies (*i.e.*, standard farm pond) (**Table 3.8**) for wettable powder and water dispersible granule formulations. For aerial applications, EFED used the American Society of Agricultural and Biological Engineers (ASABE, formerly ASAE) Fine-to-Medium droplet size category in its modeling. This drop size category is EFED's default distribution when labels do not specify application parameters. For ground applications, EFED used the ASABE Very Fine-to-Fine droplet size category with a high boom height. Again, this droplet size category is EFED's default distribution when labels do not specify the application parameters for ground applications. Negligible amount of drift is likely from granular applications; thus, drift EECs for granular formulations are not included in the AgDRIFT modeling.

Table 3.7. TerrPlant EECs for Terrestrial Plants Located Adjacent to Tebuthiuron Treated Sites.

Broadcast Application Rate (lb a.i./A)	Application Method	TerrPlant EECs (lbs a.i./A)		
		Total Loading to Dry Areas Adjacent to Treated Areas[1]	Total Loading to Semi-Aquatic Areas Adjacent to Treated Areas[2]	Drift to Adjacent Areas[3]
6	Aerial Unincorp. Spray	0.6	3.3	0.3
4		0.4	2.2	0.2
6	Ground Unincorp. Spray	0.36	3.06	0.06
4		0.24	2.04	0.04
6	Granular	0.3	3	0.0
4		0.2	2	0.0

[1] EEC = Sheet Runoff + Drift (1% for ground)
[2] EEC = Channelized Runoff + Drift (1% for ground)
[3] EEC for ground (appl. rate x 1% drift)

Table 3.8. Maximum Drift Loadings at Specific Distances for Terrestrial and Semi-Aquatic Areas and Ponds Near Tebuthiuron Use Areas.

Broadcast Application Rate (lb a.i./A)	Application Method	Distance from Edge of Field (ft)	Drift EEC		
			Dry Areas (lb a.i./A)	Wetland (lb a.i./A)	Pond (mg/L)
6.0	Ground	0	6.0	0.4	0.02
		10	1.6	0.2	0.01
		50	0.3	0.1	0.007
		100	0.1	0.08	0.004
		500	0.02	0.02	0.001
		997	0.009	0.007	0.0004
6.0	Aerial	0	3	0.8	0.04
		10	2	0.6	0.036
		50	1	0.4	0.025
		100	0.6	0.3	0.017

		500	0.1	0.1	0.005
		997	0.07	0.07	0.004
4.0	Ground	0	4.0	0.25	0.013
		10	1.0	0.15	0.008
		50	0.2	0.08	0.004
		100	0.1	0.05	0.003
		500	0.02	0.01	0.0007
		997	0.006	0.005	0.0003
4.0	Aerial	0	2	0.5	0.028
		10	1.3	0.4	0.024
		50	0.7	0.3	0.02
		100	0.4	0.2	0.01
		500	0.07	0.06	0.004
		997	0.05	0.04	0.003

The Screening Tool for Inhalation Risk (STIR v.1.0, November 19, 2010) was used to calculate an upper-bound estimate of wildlife inhalation exposure using tebuthiuron's vapor pressure and molecular weight for vapor phase exposure as well as the maximum application rate and method of application for spray drift. STIR incorporates results from several toxicity studies including acute oral and inhalation rat toxicity endpoints obtained from the "six-pack" of core studies, which is a series of six guideline studies that are submitted to the Registration Division of the Office of Pesticide Programs for technical and formulated products of a pesticide (rat LD_{50} = 388 mg/kg-bw; rat inhalation LC_{50} = 3.696 mg/L) as well as the most sensitive acute oral avian toxicity endpoint (mallard LD_{50} >2000 mg/kg-bw). Based on the results of the STIR model (**Appendix E**), exposure through inhalation of spray drift or the vapor phase of tebuthiuron is not determined to be a potential pathway of concern for either avian or mammalian species on an acute exposure basis.

The analysis of the inhalation route in STIR does not consider that aggregation with other exposure pathways such as dietary, dermal, or drinking water may contribute to a total exposure that has a potential for effects to non-target animals. However, the Agency does consider the relative importance of other routes of exposure in situations where data indicate that pesticide exposures through other routes may be potentially significant contributors to wildlife risk (USEPA 2004). The risk characterization section (**Section 4.2**), discusses the impact of consideration of other routes of exposure that have been identified as potentially important and the degree of certainty associated with screening-level risk assessment conclusions. Detailed information about STIR v.1.0, as well as the tool, can be found on EPA's website (http://www.epa.gov/pesticides/science/models_pg.htm#terrestrial).

The Screening Imbibition Program (SIP v.1.0, released June 15, 2010) was used to calculate an upper-bound estimate of wildlife drinking water exposure using tebuthiuron's solubility (*i.e.*, 2500 mg/L at 20°C), and compared to the most sensitive acute and chronic avian and mammalian toxicity endpoints. Upon results of the screening model SIP, drinking water exposure alone is a concern for birds and mammals (**Appendix F**). Tebuthiuron has a very high solubility, which is the only parameter used in estimating potential exposure, and birds and mammals are particularly sensitive to tebuthiuron on either an acute and/or chronic basis. This pathway will be explored further with the development of SIP v.2.0 in a future Ecological Risk Assessment for tebuthiuron. For a sample of the output generated by SIP v.1.0, please see **Appendix F**. Detailed information about the SIP v.1.0, as well as the tool, can be found on the EPA's website at http://www.epa.gov/pesticides/science/models_pg.htm#terrestrial.

3.3.2. Ecological Effects Characterization

In screening-level ecological risk assessments, effects characterization describes the types of effects a pesticide can have on aquatic and terrestrial organisms. This characterization is based on the registrant-submitted toxicity data for birds, mammals, fish, invertebrates, and plants for the active ingredient selected for this ecological risk assessment phase of Registration Review.

This assessment evaluates the potential for tebuthiuron to directly or indirectly affect Federally-listed species or modify designated critical habitat. As discussed, assessment endpoints include direct toxic effects on the survival, reproduction, and growth of listed entities, as well as indirect effects, such as reduction of the prey base or modification of habitat. In addition, potential modification of critical habitat is assessed by evaluating effects to the principle constituent elements (PCEs), which are components of the critical habitat areas that provide essential life cycle needs of listed entities.

As described in the Agency's Overview Document (USEPA 2004), the most sensitive endpoint for each taxon is used for risk estimation. For this assessment, evaluated taxa include freshwater and estuarine/marine fish (freshwater fish also a surrogate for aquatic phase amphibians), freshwater and estuarine/marine invertebrates, aquatic plants, birds (also surrogate for terrestrial-phase amphibians and reptiles), mammals, honeybees, and terrestrial plants.

Toxicity endpoints are established based on data generated from guideline studies submitted by the registrant, and from open literature studies that meet the criteria for inclusion into the ECOTOX database maintained by EPA/Office of Research and Development (ORD) (U.S. EPA, 2004). In general, effects data in the open literature that indicate effects at lower concentrations than the registrant-submitted data are considered. The degree to which open literature data are quantitatively or qualitatively characterized is dependent on whether the information is relevant to the assessment endpoints (survival, reproduction, and growth). For example, endpoints such as behavior modifications are likely to be qualitatively evaluated, because quantitative relationships between modifications and reduction in species survival, reproduction, and/or growth are not available. On December 24, 2013, none of the open literature that passed the ECOTOX screen obtained effects at lower concentrations than the submitted studies and thus are not used in this risk assessment.

In addition to registrant-submitted and open literature toxicity information, other sources of information, including use of the acute probit dose-response relationship to establish the probability of an individual effect and reviews of the Ecological Incident Information System (EIIS), are conducted to further refine the characterization of potential ecological effects associated with exposure to tebuthiuron. A summary of the available aquatic and terrestrial ecotoxicity information and use of the probit dose-response relationship for tebuthiuron are provided in **Section 4**, respectively.

A review of the Ecological Incident Information System (EIIS) maintained by the Agency's Office of Pesticide Programs (OPP) indicates a total of 4 reported ecological incidents associated with the use of tebuthiuron. The reported incidents involved damage to terrestrial plants. Two incidents were associated with misuse use of tebuthiuron, one to a registered use, and the legality of the used in another was not determined. In addition, there is one aggregate minor fish and wildlife incident reported for tebuthiuron in 2003 that was reported by the pesticide registrant.

Summary of Ecological Incidents Associated with Tebuthiuron Uses, By Certainty.

Incident type	Incident ID	Use Type	Legality	Certainty				
				All (excluding unlikely)	**Unlikely**	**Possible**	**Probable**	**Highly Probable**
Damage to terrestrial plants	1003503-001	Power line	Misuse (accidental)					X
	1015921-002	Agricultural area	Undetermined			X		
	1-13603-002	Rangeland	Registered use				X	
	100512-001	Right-of-way, road	Misuse (accidental)				X	

Similarly, a search of the Avian Incident Monitoring System (AIMS; http://www.abcbirds.org/abcprograms/policy/toxins/aims/aims/index.cfm) was conducted on December 24, 2013. AIMS is a database administered by the American Bird Conservancy that contains publicly available data on reported avian incidents involving pesticides. No incidents involving tebuthiuron were found.

A major degradate of tebuthiuron, identified as compound 104, was measured in a terrestrial field dissipation study accounting for up to 23% of the mass applied and was concluded to be the only degradate of toxicological concern due to the structural similarity to tebuthiuron. While similar to the parent chemical, it lacks an N-methyl group; however, it may still have the same herbicidal toxic mode of action. As of an uncertainty since the toxicity of compound 104 to plants is unknown, EFED presumes that the degradate has the equivalent toxicity of its parent compound to terrestrial plants. Previous risk assessments indicate the parent compound resulted in LOC exceedances for terrestrial plants; thus, under this presumption, LOC exceedances would be expected with degradate compound 104. Additional data testing with the degradate compound 104 (*e.g.*, OCSPP 850.4100 and/or 850.4150 Tier II terrestrial plant toxicity test) would be needed to reduce the uncertainty associated with this presumption.

3.3.2.1. Aquatic Effects Characterization

The most sensitive acute and chronic effects measurement endpoints associated with tebuthiuron exposure to freshwater and estuarine/marine species are summarized in **Table 3.9.** Selected effects endpoints for the risk assessment are from acceptable and supplemental studies for tebuthiuron and are briefly described below.

Based on the available toxicity data, tebuthiuron is classified as practically non-toxic to aquatic organisms with the exception of the slightly toxic toxicity classification to estuarine/marine invertebrates. In addition, freshwater fish are surrogates for aquatic-phase amphibians in the absence of amphibian-specific data; therefore, using the acute toxicity data with freshwater fish, tebuthiuron would be classified as practically non-toxic to aquatic-phase amphibians. Chronic toxicity data were only available for freshwater fish and invertebrates, for which effects on reproduction and growth were observed in the invertebrate study and growth in the fish study. Acute-to-Chronic Ratio calculations were used to estimate the NOAEC for chronic effects to estuarine/marine fish using rainbow trout data and to invertebrates using data from the daphnid studies.

Summaries of the ecological toxicity studies are provided in **Appendix G**.

Table 3.9. Most Sensitive Acute and Chronic Toxicity Data for Aquatic Organisms Exposed to Tebuthiuron.				
Exposure Scenario	**Species**	**Affected Endpoint**	**Toxicity Measurement**	**MRID (Classification)**
Freshwater Fish				
Acute	Bluegill sunfish (*Lepomis macrochirus*)	Mortality	96-hr LC_{50} = 106 mg a.i./L	40098001 (acceptable)
Chronic	Fathead minnow (*Pimephales promelas*)	Sub-lethal	33-day NOAEC = 9.3 mg a.i./L (length)	00090084 (acceptable)
Freshwater Invertebrates				
Acute	Water flea (*Daphnia* spp.)	Immobility	48-hr EC_{50} = 297 mg a.i./L	00041694 (acceptable)
Chronic		Sub-lethal	21-day NOAEC = 21.8 mg a.i./L (growth, fecundity, time of first brood release, young per adult)	00138700 (acceptable)
Estuarine/Marine Fish				
Acute	Sheepshead minnow (*Cyprinodon variegates)*	Mortality	96-hr LC_{50}>98 mg a.i./L	48722702 (acceptable)
Chronic		No data available	Estimated NOAEC >18 mg a.i./L	ACR[1]
Estuarine/Marine Invertebrates				
Acute	Pink shrimp (*Penaeus duorarum)*	Mortality	96-hr LC_{50} = 62 mg a.i./L	00041684 (acceptable)
Chronic		No data available	Estimated NOAEC = 4.56 mg a.i./L	ACR[1]
Aquatic Plants				
7-day exposure	Duckweed (*Lemna gibba*)	Frond count	7-day EC_{50} = 0.13 mg a.i./L NOAEC = 0.05 mg a.i./L	41080404 (supplemental)
96-hour exposure	Marine diatom (*Skeletonema costatum*)	Cell density	96-hr EC_{50} = 0.05 mg a.i./L NOAEC = 0.038 mg a.i./L	41080402 (supplemental)

[1] Estimated value based on Acute to Chronic Ratio (ACR) method using rainbow trout data; ACR = 5.5. Sheepshead minnow NOAEC = (LC_{50} of >98 mg/L ÷ 5.5) = >18 mg/L

[2] Estimated value based on Acute to Chronic Ratio (ACR) method using daphnid data; ACR = 13.6. Shrimp NOAEC = (LC_{50} of 62 mg/L ÷ 13.6) = 4.56 mg/L

Freshwater Fish, Acute Effects

Fish toxicity studies using the technical grade active ingredient (TGAI) were submitted to establish the acute toxicity of tebuthiuron to fish. The preferred test species are the rainbow trout and bluegill sunfish. Results of the acute studies with freshwater fish indicate the LC_{50} value of 106 mg a.i./L for the sunfish is the most sensitive endpoint for fish (**Table 3.10**). As a result, tebuthiuron is categorized as practically nontoxic to fish. The sunfish LC_{50} will be used to evaluate potential acute effects of tebuthiuron to freshwater fish.

Table 3.10. Freshwater Fish Acute Toxicity Profile for Tebuthiuron.

Species	% a.i.	LC_{50} (mg a.i./L)	Toxicity Category	MRID No. Author/Year	Study Classification
Rainbow trout (*Oncorhynchus mykiss*)	98	143[A]	Practically nontoxic	00020661 Anon. (1972)	Acceptable
Bluegill sunfish (*Lepomis macrochirus*)	98	106[B]	Practically nontoxic	00020661 Anon. (1972)	Acceptable
Goldfish (*Carassius auratus*)	98	>160	Practically nontoxic	00020661 Anon. (1972)	Supplemental[1]
Fathead minnow (*Pimephales promelas*)	98 80 20 (pellet)	>180	Practically nontoxic	00041685 Hamelink and Kehr (1976)	Supplemental[2]

[A] Trout 95% Confidence Interval (C.I.) = 118-224 mg a.i./L; slope = N/A (binominal)
[B] Sunfish 95% C.I. = 87-120 mg a.i./L; slope = N/A (binomial)
[1] Dilution water, pH and dissolved oxygen were not measured; goldfish is not a recommended species.
[2] Inadequate reporting of test conditions and aeration during the test.

Freshwater Fish, Chronic Effects

Laboratory toxicity studies using the TGAI were submitted to establish the chronic toxicity of tebuthiuron to freshwater fish. The preferred test species is the most sensitive fish of the freshwater fish acute toxicity tests; when a 96-hour LC_{50} is not available, rainbow trout or fathead minnow is preferred. Results of the chronic studies with the TGAI to freshwater fish indicate the lowest NOAEC value to be 9.3 mg a.i./L (**Table 3.11**). Thus, the NOAEC of 9.3 mg a.i./L will be used to evaluate potential chronic effects of tebuthiuron to freshwater fish.

Table 3.11. Freshwater Fish Chronic Toxicity Profile for Tebuthiuron.

Species	% a.i.	LOAEC / NOAEC (mg a.i./L)	Endpoint Affected	MRID No. Author/Year	Study Classification
Rainbow trout (*Oncorhynchus mykiss*)	98	52/26	Adult survival and length	00090083 Sauter, Meyerhoff, Todd *et al*. (1981)	Acceptable
Fathead minnow *(Pimephales promelas)*	98	18/9.3	Length	00090084 Sauter, Meyerhoff, Todd *et al*. (1981)	Acceptable

Freshwater Invertebrates, Acute Effects

A toxicity study using the TGAI was submitted to establish the acute toxicity of tebuthiuron to freshwater invertebrates. Daphnids are the preferred test species. Results of the acute study with freshwater invertebrates indicate an EC_{50} value of 297 mg a.i./L (**Table 3.12**), which categorizes tebuthiuron as practically nontoxic to freshwater invertebrates. Thus, the EC_{50} will be used to evaluate potential acute effects of tebuthiuron to freshwater invertebrates.

Table 3.12. Freshwater Invertebrate Acute Toxicity Profile for Tebuthiuron.

Species	% a.i.	EC_{50} (mg a.i./L)	Toxicity Category	MRID No. Author/Year	Study Classification
Water flea (*Daphnid magna*)	99.2	297[A]	Practically nontoxic	00041694 Hamelink, Todd, Brannon *et al.* (1978)	Acceptable

[A] *D. magna* 95% Confidence Interval = 279-316 mg a.i./L; Probit slope = 13.3 (9.06-17.6)

Freshwater Invertebrates, Chronic Effects

A laboratory toxicity study using the TGAI was submitted to establish the chronic toxicity of tebuthiuron to freshwater invertebrates. The preferred test species is the water flea. Results of the reproduction study with freshwater invertebrates indicate a NOAEC value of 21.8 mg a.i./L (**Table 3.13**). The NOAEC will be used to evaluate potential chronic effects of tebuthiuron to freshwater invertebrates.

Table 3.13. Freshwater Invertebrate Chronic Toxicity Profile for Tebuthiuron.

Species	% a.i.	LOEAC / NOAEC (mg a.i./L)	Endpoint Affected	MRID No. Author/Year	Study Classification
Water flea *(Daphnia magna)*	97.4	44.2/21.8	Time to first brood release, offspring per adult and length	000138700 Grothe and Meyerhoff. (1983)	Acceptable

Estuarine/Marine Fish, Acute Effects

An estuarine/marine fish toxicity study using the TGAI was submitted to establish the acute toxicity of tebuthiuron to estuarine/marine fish. The preferred test species is the Atlantic silversides; however, the registrant submitted an acceptable species, the Sheepshead minnow. Results of the acute study indicate an LC_{50} value of >98 mg a.i./L (**Table 3.14**). With no mortality at and up to 98 mg a.i./L, tebuthiuron is categorized as practically nontoxic to estuarine/marine fish. The LC_{50} value of >98 mg a.i./L will be used to evaluate potential acute effects of tebuthiuron to estuarine/marine fish.

Table 3.14. Estuarine/Marine Fish Acute Toxicity Profile for Tebuthiuron.					
Species	**% a.i.**	**LC_{50} (mg a.i./L)**	**Toxicity Category**	**MRID No. Author/Year**	**Study Classification**
Sheepshead minnow *(Cyprinodon variegates)*	99.8	>98	Practically nontoxic	48722702 Fournier (2011)	Acceptable

Estuarine/Marine Fish, Chronic Effects

No chronic ecological effects studies of tebuthiuron using estuarine/marine fish were submitted. The Acute-to-Chronic Ratio (ACR) approach was used to estimate the chronic toxicity to estuarine/marine fish in absence of data. The ACR using rainbow trout acute and chronic data is 5.5. Employing the ACR of 5.5 to the sheepshead LC_{50} of >98 mg a.i./L calculates a chronic toxicity value of >18 mg a.i./L for estuarine/marine fish. The NOAEC of >18 mg a.i./L will be used to evaluate potential chronic effects of tebuthiuron to estuarine/marine fish.

Estuarine/Marine Invertebrates, Acute Effects

Toxicity studies using the TGAI were submitted to establish the acute toxicity of tebuthiuron to estuarine/marine invertebrates. The preferred test species are the mysid shrimp and Eastern oyster (shell deposition). Results of the acute studies indicate the lowest LC_{50} value for estuarine/marine invertebrates to be 62.3 mg a.i./L (**Table 3.15**). As of a result, tebuthiuron is categorized as slightly toxic to estuarine/marine invertebrates. The LC_{50} of 62.3 mg a.i./L will be used to evaluate potential acute effects of tebuthiuron to estuarine/marine invertebrates.

Table 3.15. Estuarine/Marine Invertebrate Acute Toxicity Profile for Tebuthiuron.					
Species	**% a.i.**	**LC_{50}/EC_{50} (mg a.i./L)**	**Toxicity Category**	**MRID No. Author/Year**	**Study Classification**
Pink shrimp *(Penaeus duorarum)*	98	62.3[A]	Slightly toxic	00041684 Heitmuller and Parrish (1976)	Acceptable
Fiddler crab (*Uca pugilator*)		>100	Practically nontoxic		Supplemental[1]
Eastern oyster [embryos] (*Crassostrea virginica*)		>100 [B]	Practically nontoxic		Acceptable[2]
Eastern oyster [shell deposition] (*Crassostrea virginica*)	99.8	>95	Practically nontoxic	48722701 York (2011)	Acceptable

[A] Shrimp 95% Confidence Interval = 38.7-90.1 mg a.i./L; slope = 4.5 (2.1-6.9)

Table 3.15. Estuarine/Marine Invertebrate Acute Toxicity Profile for Tebuthiuron.					
Species	**% a.i.**	**LC_{50}/EC_{50} (mg a.i./L)**	**Toxicity Category**	**MRID No. Author/Year**	**Study Classification**

[B] The 48-hour LC_{50} is actually between 180 and 320 mg a.i./L due to 100% mortality at 320 mg a.i./L and 0% mortality at 180 mg a.i./L. Because a definite LC_{50} could not be calculated, the EPA reviewer determined a LC_{50} of >100 mg a.i./L which still classifies tebuthiuron as practically nontoxic to oyster embryos.

[1] Not a recommended species

[2] Bivalve acute toxicity study (OCSPP 850.1055; embryo-larval)

Estuarine/Marine Invertebrates, Chronic Effects

No chronic ecological effects studies of tebuthiuron using estuarine/marine invertebrates were submitted. The Acute-to-Chronic Ratio (ACR) approach was used to estimate the chronic toxicity to estuarine/marine invertebrates in absence of data. The ACR using Daphnia acute and chronic data is 13.6. Employing the ACR of 13.6 to the shrimp LC_{50} of 62.3 mg a.i./L calculates a chronic toxicity value of 4.56 mg a.i./L for estuarine/marine invertebrates. The NOAEC of 4.56 mg a.i./L will be used to evaluate potential chronic effects of tebuthiuron to estuarine/marine invertebrates.

Effects to Aquatic Vascular and Non-vascular Plants

Tebuthiuron studies were submitted for a freshwater vascular plant (duckweed, *Lemna gibba*) and four phytoplanktonic nonvascular plants: green algae (*Selenastrum capricornutum*), cyanobacteria (*Anabaena flos-aquae*), freshwater diatom (*Navicula pelliculosa*) and marine alga (*Skeletonema costatum*) (**Table 3.16**).

Aquatic plant toxicity studies using the TGAI were submitted to establish the toxicity of tebuthiuron to vascular and non-vascular species. The aquatic vascular plant duckweed EC_{50} and NOAEC of 0.13 and 0.05 mg a.i./L, respectively, and the most sensitive EC_{50} of aquatic nonvascular plants studies using the marine diatom EC_{50} and NOAEC of 0.05 and 0.038 mg a.i./L, respectively, will be used to evaluate potential effect of tebuthiuron to aquatic plants. While the green algae and marine diatom, when based on the EC_{50}, were the most sensitive nonvascular plants; the No Effect level for the freshwater green algae may be more sensitive than the marine diatom; however, the results of the algae study could not be verified, the NOAEC for marine diatom was determined to be more reliable than the algae's NOAEC.

EC_{50} values of 0.13 and 0.05 mg a.i./L (**Table 3.16**) will be used to evaluate potential effects of tebuthiuron to non-listed aquatic vascular and non-vascular plants, respectively. Corresponding NOAEC values of 0.05 and 0.038 mg a.i./L will be used to evaluate potential effects of tebuthiuron to listed aquatic vascular and nonvascular plants, respectively.

Table 3.16. Aquatic Plant Toxicity Profile for Tebuthiuron.

Species	% a.i.	EC_{50} (mg a.i./L)	NOAEC (mg a.i./L)	MRID No. Author/Year	Study Classification
Vascular Plants					
Duckweed (*Lemna gibba*)	99.08	0.13[A]	0.05	41080404 Negilski and Cocke (1989)	Supplemental[1]
Non-Vascular Plants					
Marine diatom (*Skeletonema costatum*)	99.08	0.05[B]	0.038	41080402 Negilski and Cocke (1989)	Supplemental[1]
Freshwater blue-green algae (*Anabaena flos-aquae*)	99.08	0.81[C]	<0.31 (EC_{05} = 0.03)	41080401 Negilski, Grothe and Cocke (1989)	Supplemental[1]
Freshwater diatom (*Navicula pelliculosa*)	99.08	0.09[D]	0.056	41080403 Negilski and Cocke (1989)	Supplemental[1]
Freshwater green algae (*Selenastrum capricornutum*)	98	0.05	0.013	00138697 Todd, Meyerhoff, Grothe, *et al.* (1983)	Supplemental[1,2]

[A] Duckweed 95% Confidence Interval (C.I.) = 0.06-0.26 mg a.i./L

[B] Marine diatom 95% C.I. = 0.04-0.06 mg a.i./L

[C] Blue-green algae 95% C.I. = 0.59-1.12 mg a.i./L

[D] Freshwater diatom 95% C.I. = 0.08-0.14 mg a.i./L

[1] Three replicates per treatment level were used. EPA requires four replicates per level.

[2] Results could not be verified since raw data were not provided. Results are based on a 5-day exposure.

3.3.2.2. Terrestrial Effects Characterization

The most sensitive acute and chronic effects measurement endpoints associated with tebuthiuron exposure to terrestrial species are summarized in **Table 3.17.** Selected effects endpoints for the risk assessment are from acceptable and supplemental studies for tebuthiuron and are described below.

Overall, tebuthiuron is practically nontoxic to mallard ducks on an acute basis. Tebuthiuron caused no mortality or sub-lethal effects up to and including 2,000 mg a.i./kg bw and 5093 mg a.i./kg diet to waterfowl via oral and dietary routes, respectively; and up to 500 mg a.i./kg bw and 5113 mg a.i./kg diet for upland game birds. On the other hand, tebuthiuron is slightly toxic to small birds (*i.e.*, passerines) on a dietary basis. In addition, birds also act as surrogates for reptiles and terrestrial-phase amphibians in the absence of taxa specific data; therefore, using the acute toxicity data with passerines, tebuthiuron would be classified as slightly toxic to reptiles and terrestrial-phase amphibians of similar body weight. Observations of reproductive effects in birds were as low as 500 mg a.i./kg diet; the resulting NOAECs for two avian species were both 100 mg a.i./kg diet.

Tebuthiuron is moderately toxic to mammals on an acute oral basis (female LD_{50} = 387.5 mg a.i/kg-bw; male LD_{50} = 477.5 mg a.i/kg-bw). In the chronic 2-generation studies, reproductive effects are as low as 30 mg a.i./kg/day (NOAEL = 14 mg a.i./kg/day), based on decreased body weight and decreased body weight gains for female rats.

Results of the honeybee acute contact test with tebuthiuron indicate the TGAI is practically nontoxic to honeybees (LD_{50} = >100 µg a.i./bee).

As may be anticipated with an herbicide, terrestrial plants were affected at the seedling and the 3-leaf plant stages with the lowest EC_{25}'s at 0.018 and 0.16 lb a.i./A, respectively.

Table 3.17. Most Sensitive Acute and Chronic Toxicity Data for Terrestrial Animals and Plants Exposed to Tebuthiuron.

Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value	MRID (Classification)
Mammals				
Acute (Dose-based)	Laboratory rat (*Rattus norvegicus*)	Single oral dose	Female LD_{50} = 387.5 mg a.i./kg-bw	40583901 (acceptable)
Chronic (Dietary-based)		One-generation	LOAEL = 400 ppm NOAEL = 200 ppm (14 mg/kg/day)	00090108 (acceptable)
Birds				
Acute (Dose-based)	Mallard duck (*Anas platyrhynchus*)	14-day single oral dose	LD_{50} >2000 mg a.i./kg bw	00041692 (acceptable)
Acute (Dietary-based)	Zebra finch (*Taeniopygia guttata*)	8-day dietary	LC_{50} = 1465 mg a.i./kg-diet	48928201 (acceptable)
Chronic (Dietary-based)	Mallard duck (*Anas platyrhynchus*)	One-generation	NOAEC = 100 mg a.i./kg-diet	000104243 (acceptable)
Terrestrial Plants				
Seedling emergence	Ryegrass (monocot)	14 days	EC_{25} = 0.27 lbs a.i./A NOAEC = 0.25 lbs a.i./A	48722703 (supplemental)
	Carrot (dicot)		EC_{25} = 0.018 lbs a.i./A EC_{05} = 0.0032 lbs a.i./A*	
Vegetative Vigor	Ryegrass (monocot)		EC_{25} = 0.30 lbs a.i./A NOAEC = 0.12 lbs a.i./A	48722704 (supplemental)
	Sugarbeet (dicot)		EC_{25} = 0.16 lbs a.i./A NOAEC = 0.062 lbs a.i./A	

Table 3.17. Most Sensitive Acute and Chronic Toxicity Data for Terrestrial Animals and Plants Exposed to Tebuthiuron.				
Exposure Scenario	**Species**	**Exposure Duration**	**Toxicity Reference Value**	**MRID (Classification)**
Beneficial Insects				
Contact	Honey bee	48 hours	LD_{50} >100 µg a.i./bee	40840401 (acceptable)

* The NOAEC was above the EC_{25}; thus, the EC_{05} was used instead.

Birds, Acute Oral

An acute oral toxicity study using the TGAI is required to establish the acute toxicity of tebuthiuron to birds. The preferred guideline bird test species is either mallard duck (a waterfowl) or Northern bobwhite quail (an upland game bird), and a passerine bird. The submitted acute data indicate that the TGAI is categorized as practically nontoxic to waterfowls (LD_{50} >2000 mg a.i./kg bw, the maximum dose tested), and no effects to domestic chickens and upland game birds were observed at and up to 500 mg a.i./kg bw (**Table 3.18**).

However, for passerines, regurgitation occurred at all test doses of an acute oral range-finding study, preventing the estimation of an oral LD_{50}; therefore the registrant opted to conduct a dietary-based study using OCSPP 850.2200 with food consumption closely monitored. The study design switch was intended to estimate an oral LD_{50} value for passerines using the LC_{50} data from the passerine dietary study (MRID 48928201; **Table 3.19**). An oral LD_{50} could not be estimated due to variability in the study results; thus, the dose-based oral toxicity of tebuthiuron to passerines is unknown. The toxicity of the active ingredient to passerines is discussed in more detail in the avian acute dietary toxicity profile following this section.

Thus, with no mortality at doses as high as 2,000 mg a.i./kg-bw, the LD_{50} of >2000 mg a.i./kg-bw will be used to evaluate potential acute effects of the TGAI to birds via the oral route. The available avian acute oral toxicity data are summarized in **Table 3.18.**

Table 3.18. Avian Acute Oral Toxicity Profile for Tebuthiuron.					
Species	**% a.i.**	**LD_{50} (mg a.i./kg bw)**	**Toxicity Category**	**MRID No. Author/Year**	**Study Classification**
Domestic chicken (*Gallus sp.*)	98	>500	No effects up to 500 ppm	00020661 Todd, Kehr, West and *et al*. (1972)	Supplemental[1]
Mallard duck (*Anas platyrhynchos*)	98	>2000	Practically nontoxic	00041692 Kehr, Hamelink, Todd and *et al*. (1978)	Acceptable
	98	>500	No effects up to 500 ppm	00020661 Todd, Kehr, West and *et al*. (1972)	Supplemental[1]

Table 3.18. Avian Acute Oral Toxicity Profile for Tebuthiuron.					
Species	**% a.i.**	**LD_{50} (mg a.i./kg bw)**	**Toxicity Category**	**MRID No. Author/Year**	**Study Classification**
Northern bobwhite quail *(Colinus virginianus)*	98	>500	No effects up to 500 ppm	00020661 Todd, Kehr, West and *et al*. (1972)	Supplemental[1]

[1] The highest concentration was below the recommended limit dose of 2000 mg a.i./kg bw.

Birds, Subacute Dietary

Dietary studies using the TGAI are required to establish the subacute toxicity of tebuthiuron to birds. The preferred test species are mallard duck (waterfowl) and bobwhite quail (upland game bird). The submitted data indicate no mortality occurred and that the 8-day acute dietary LC_{50} for duck and quail were >5093 and >5113 mg a.i./kg diet, respectively, the maximum concentrations tested. The TGAI is categorized as practically non-toxic to upland game birds and waterfowl on a subacute dietary basis (**Table 3.19**).

While results indicate the duck and quail were equally insensitive to the TGAI; passerines were slightly sensitive to tebuthiuron as mortality and extremely low food consumption were observed in the three highest concentrations (1590, 2870, and 5380 mg a.i./kg-diet). At the 1590 mg a.i./kg-diet treatment level, 8 birds died (80%). At the 2870 mg a.i./kg-diet treatment level, two birds were taken off of treated feed before the full five day exposure was complete due to extremely reduced feed consumption and were counted as mortalities. Of the 8 birds that stayed on the treated diet, 7 birds died (87.5%). At the highest treatment level, two birds died on Day 2 of the test and the other eight birds were switched to untreated feed due to overall extreme reduction in feed consumption. One bird died on Day 4. All other surviving birds on untreated food were normal in appearance and behavior from Day 4 to test termination but were considered to have died (100%) due to insufficient caloric intake to sustain life had the birds remained on treated food. Clinical signs of toxicity were observed as follows: at 497 mg a.i./kg-diet, up to 50% of birds displayed slightly ruffled appearance and wing droop between Days 2 and 6; at 895 mg a.i./kg-diet, up to 60% of birds displayed ruffled appearance and wing droop between Days 2 and 7; at 1590 mg a.i./kg-diet, all birds displayed at least one clinical sign of toxicity (ruffled appearance, lethargy, and wing droop) by Day 4; at 2870 mg a.i./kg-diet, all birds were noted with at least one clinical sign of toxicity (ruffled appearance, lethargy, wing droop, loss of coordination, prostrate posture, and loss of righting reflex) or died by Day 3; and at 5380 mg a.i./kg-diet, all birds were noted with ruffled appearance by the afternoon of Day 1. Due to the mortality pattern that occurred, there was not a dose-response effect. Not all mortalities were related to the toxicity of tebuthiuron but were a result of avoidance of the treated feed. Assuming all birds removed from treated diets because of reduced feed consumption would have died, the resulting LC_{50} is 1465 mg a.i./kg diet for passerines.

Therefore, the LC_{50} value of 1465 mg a.i./kg-diet will be used to evaluate potential acute effects of the TGAI to birds via the dietary route. The available avian subacute dietary studies are summarized in **Table 3.19**.

Table 3.19. Avian Acute Dietary Toxicity Profile for Tebuthiuron					
Species	**% a.i.**	**Nominal LC_{50} (mg a.i./kg diet)**	**Toxicity Category**	**MRID No. Author/Year**	**Study Classification**
Zebra finch (*Taeniopygia guttata)*	99.8	1465[A]	Slightly toxic	48928201 Hubbard, Martin and Beavers (2012)	Acceptable
Mallard duck (*Anas platyrhynchos*)	98	>2500	No effects up to 2500 mg a.i./kg diet	00041680/ (00041693; addendum) West and Hamelink (1976) / Kehr, Brannon, Todd and *et al.* (1978)	Supplemental[1]
	99.1	>5093	Practically nontoxic	40601001 Negilski, Grothe & Meyeroff (1988)	Acceptable
Northern bobwhite quail *(Colinus virginianus)*	98	>2500	No effects up to 2500 mg a.i./kg diet	00041681/ (00041693; addendum) West and Hamelink. (1976) / Kehr, Brannon, Todd and *et al.* (1978)	Supplemental[1]
	99.1	>5113	Practically nontoxic	40601002 Negilski, Grothe & Meyeroff (1988)	Acceptable

[A] Finch 95% Confidence Interval = 1145 to 1883 mg a.i./L; slope = 6.5 (2.997-10.03)

[1] The concentrations used (when adjusted for active ingredient) did not produce a precise LD_{50} and the highest concentration was below 5000 mg a.i./kg bw.

Birds, Reproduction

Avian reproduction studies using the TGAI are required to establish the chronic toxicity of tebuthiuron to birds (**Table 3.20**). The preferred test species are mallard duck and bobwhite quail. The lowest reproduction NOAEC of 100 mg a.i./kg diet will be used to evaluate potential chronic effects of the TGAI to birds. The available avian reproduction studies are summarized in **Table 3.20**.

Bobwhite quail showed dose-dependent effects for offspring survival. At 903 and 1550 mg a.i./kg diet, the offspring survival (14-day hatchlings per number hatched) was slightly (4-7%), but significantly reduced, compared to the control ($p<0.05$; Jonckheere-Terpstra test). Also, at the 1550 mg a.i./kg diet level, egg production was reduced 23%, from an average of 44.8 eggs laid per pen in the control group to 34.7 eggs laid per pen in the treated group ($p<0.05$; Jonckheere-Terpstra test); both the study author and reviewer concluded that this effect was treatment-related, despite the non-monotonicity of the data. No statistically significant differences in eggshell thickness were observed between the control group and any of the treatment groups. Adult male body weight gain was significantly reduced in a dose-dependent manner 53-121% at all treated levels, relative to the negative control ($p<0.05$, William's test). Adult female body weight was significantly reduced at the 1550 mg a.i./kg diet level, relative to the control ($p<0.01$; Jonckheere-Terpstra test). No statistically significant differences were observed between the control group and any of the treated groups for food consumption. Offspring body weights were significantly reduced in a dose-dependent manner, with reductions from control detected at the 903 and 1550 mg a.i./kg diet levels for hatchling body weights ($p<0.01$; Jonckheere-Terpstra test) and at the 1550 mg a.i./kg diet level for 14-day old survivor weight ($p<0.05$; William's test).

In the mallard study, a statistically significant ($p<0.05$) dose-dependent reduction in hatchling body weight and eggshell thickness was observed at 1550 mg a.i./kg diet compared to the controls. There were statistically significant ($p<0.05$; Williams test, 26-41%) reductions from control in egg production (eggs laid per pen) in the 500, 903 and 1550 mg a.i./kg diet groups. A slight (<1%) reduction from control in eggs not cracked per eggs laid was detected at the lowest treatment level ($p = 0.04$), but was not considered to be treatment-related.

Table 3.20. Avian Reproduction Toxicity Profile for Tebuthiuron.

Species	% a.i.	NOAEC / LOAEC (mg a.i./kg-diet)	Affected endpoints	MRID no. Author/Year	Study classification
Northern bobwhite quail *(Colinus virginianus)*	96.4	100/>100	None	00104243 Fink, Beavers & Brown (1978)	Acceptable
	99.8	<500/500	Eggs laid per pen, 14-day hatchlings per number hatched, hatchling body weight, 14 day survivor weight, female weight gain and male weight gain.	48928203 Frey *et al.* (2012)	Supplemental[1]
Mallard duck (*Anas platyrhynchos*)	96.4	100/>100	None	00093690 Fink, Beavers & Brown (1978)	Acceptable
	99.8	<500/500	Eggs laid per pen, hatchling weight, and eggshell thickness	48928202 Frey *et al.* (2012)	Supplemental[1]

[1] An NOAEC was not available.

Mammals, Acute Oral

Wild mammal testing is required on a case-by-case basis, depending on the results of lower Tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. These toxicity values are reported below in **Table 3.21**.

The results indicate tebuthiuron is categorized as moderately toxic (female LD_{50} = 387.5 mg a.i/kg-bw; male LD_{50} = 477.5 mg a.i/kg-bw) to small mammals on an acute oral basis. The LD_{50} value of 387.5 mg a.i./kg-bw will be used to evaluate potential acute effects to mammals.

Table 3.21. Mammalian Acute Oral Toxicity Profile for Tebuthiuron.

Species	% a.i.	Test Type	LD_{50} (mg a.i./kg bw)	Affected Endpoints	MRID No. Author, Year	Toxicity Category
Rat (Fischer 344)	99.1	acute oral	Females = 387.5 Males = 477.5	Mortality	40583901 Negilski and Hawkins (1988)	Moderately toxic

Mammals, Reproduction

In the 2-generation reproduction study (**Table 3.22)**, rats exposed to the TGAI showed no reproductive or offspring effects; however, reduced body weight and decreased body weight gains were observed. Parental female rats in the 200 and 400 ppm groups had mean weekly body weights 7-9% (not biologically significant) and 8-13% ($p<0.01$ or <0.05), respectively, less than the control group throughout the premating period starting with day 21 for the 200 ppm group and day 7 for the 400 ppm group. Weight gain over the entire premating period was 7% (not significant) less than control for 200 ppm group and 14% ($p<0.05$) less for the 400 ppm group. The lowest NOAEC value of 200 ppm (14 mg a.i./kg-bw/day) will be used to evaluate potential chronic effects of the TGAI to mammals. The available mammalian reproduction studies are summarized in **Table 3.22**.

Table 3.22. Mammalian Reproductive Toxicity Profile for Tebuthiuron.

Species	% a.i.	Test Type	Toxicity ppm (mg a.i./kg bw/day)		Affected Endpoints	MRID No.
Rat (Wistar)	98	2-generation	Parental	Female NOAEL = 200 (14) Male NOAEL = 400 (30) Female LOAEL = 400 (30) Male LOAEL = >400 (>30)	Decreased body weight and body weight gains for female rats	00090108
			Reproductive	NOAEL = 400 (30) LOAEL = >400 (>30)	None	
			Offspring	NOAEL = 400 (30) LOAEL = >400 (>30)	None	

Beneficial Insects, Acute

A honeybee acute contact study using tebuthiuron is required to establish the toxicity of the TGAI to beneficial insects because of outdoor uses that will result in honeybee exposure (**Table 3.23**). The acute contact LD_{50}, using the honey bee, *Apis mellifera*, is derived from a laboratory study designed to estimate the quantity of toxicant required to cause 50% mortality in a test population of bees. Results of the acute contact study with honeybees indicate tebuthiuron is practically non-toxic to bees on a contact exposure basis. The available honeybee acute contact study is summarized in **Table 3.23**.

Table 3.23. Honeybee Acute Contact Toxicity Profile for Tebuthiuron.					
Species	**% a.i.**	**LD_{50} (µg a.i./bee)**	**Toxicity Category**	**MRID No.**	**Study Classification**
Honey bee (*Apis mellifera*)	99.1	>100	Practically nontoxic	40840401 Hoxter and Jaber (1988)	Acceptable

Terrestrial Plants, Seedling Emergence and Vegetative Vigor

Terrestrial plant studies are required for all terrestrial outdoor pesticides. Tier II terrestrial plant toxicity studies were conducted to establish the toxicity of tebuthiuron (**Table 3.24**) to non-target terrestrial plants tested at 4 lb a.i./A. The recommendations for seedling emergence and vegetative vigor studies are for testing of (1) six species of at least four dicotyledonous families, one species of which is soybean (*Glycine max*), and the second of which is a root crop, and (2) four species of at least two monocotyledonous families, one of which is corn (*Zea mays*). The tests indicate seedlings and young plants for each species were generally equally sensitive when exposed to tebuthiuron, except for dicots in which seedlings were more sensitive. EC_{50} values were used to evaluate potential effects of tebuthiuron to <u>non-listed</u> terrestrial plant species. Corresponding NOAEC values were used to evaluate potential effects of tebuthiuron to <u>listed</u> terrestrial plant species.

Results of the seedling emergence test indicate the most sensitive monocot species, based on fresh weight, was ryegrass with an EC_{25} of 0.27 lb a.i./A and a NOAEC of 0.25 lb a.i./A. The most sensitive dicot species, based on fresh weight, was carrot with an EC_{25} of 0.018 lb a.i./A and a NOAEC of 0.031 lb a.i./A.

In the vegetative vigor test, the most sensitive monocot species, based on fresh weight, was ryegrass with an EC_{25} of 0.30 lb a.i./A and a NOAEC of 0.12 lb a.i./A. The most sensitive dicot species, based on fresh weight, was sugarbeet with an EC_{25} of 0.16 lb a.i./A and a NOAEC of 0.062 lb a.i./A

Both studies are scientifically sound but do not fulfill the guidelines (OCSPP 850.4100 and 850.4150) and are classified as supplemental because fresh weight instead of dry weight was measured, and only the three highest test levels instead of all test levels were verified.

EC_{25} values will be used to evaluate potential effects of tebuthiuron to non-listed plants, respectively. Corresponding NOAEC values will be used to evaluate potential effects of tebuthiuron to listed plants, respectively.

The description and classification of the available terrestrial plants studies are summarized in **Table 3.24**.

Table 3.24. Summary of Tier II Seedling Emergence and Vegetative Vigor Toxicity Profile for Tebuthiuron. [A]

	Seedling Emergence *				**Vegetative Vigor** **			
Species	**Endpoint**	**NOAEC**	**EC_{05}**	**EC_{25}**	**Endpoint**	**NOAEC**	**EC_{05}**	**EC_{25}**
Onion	Fresh weight	0.25	0.23	0.46	Fresh weight	0.25	0.25	0.57
Corn	Shoot length	2.0	1.8	3.1	Fresh weight	2.0	1.8	2.6
Oat	Fresh weight	0.50	0.27	0.52	Shoot length	0.5	0.16	0.93
Ryegrass	Fresh weight	0.25	0.12	0.27	Fresh weight	0.12	0.065	0.30
Carrot	Fresh weight	0.031	0.0032	0.018	Fresh weight	0.50	0.30	0.52
Cucumber	Fresh weight	0.12	0.13	0.33	Fresh weight	0.12	0.097	0.28
Cabbage	Fresh weight	0.12	0.14	0.23	Fresh weight	0.12	0.18	0.32
Soybean	Fresh weight	1.0	0.79	1.2	None	0.12/0.50 /2.0[B]	NC	NC
Sugarbeet	Fresh weight	0.12	0.11	0.20	Fresh weight	0.062	0.053	0.16
Tomato	Fresh weight	0.062	0.13	0.26	Fresh weight	0.25	0.25	0.43

* 22.1% a.i; MRID 48722703, Bergfield 2012.

** 22.1% a.i; MRID 48722704, Bergfield 2012.

NC – Not calculated or converged.

[A] Measured concentrations for sugarbeet, tomato, and cabbage were 0.0020, 0.0039, 0.0078, 0.016, 0.031, 0.062, 0.12, 0.25, 0.50, and 1.0 lb a.i./A. For soybean, measured concentrations were 0.0020, 0.0039, 0.0078, 0.016, 0.031, 0.062, 0.12, 0.25, 0.50, 1.0, and 2.0 lb a.i./A. For onion, ryegrass, oat, carrot, and cucumber, measured concentrations were 0.0078, 0.016, 0.031, 0.062, 0.12, 0.25, 0.50, 1.0, 2.0, and 4.0 lb a.i./A. The measured concentrations for corn were 0.12, 0.25, 0.50, 1.0, 2.0, and 4.0 lb ai/A.

[B] NOAEC values for fresh weight, shoot length, and survival, respectively.

4. Risk Characterization

4.1. Risk Estimation

Toxicity data and exposure estimates are used to evaluate the potential for adverse ecological effects on non-target species. This assessment for tebuthiuron relies on the deterministic RQ method to provide a metric of potential risks. The RQ provides a comparison of exposure estimates to toxicity endpoints (*i.e.*, the estimated exposure concentrations are divided by acute and chronic toxicity values). The resulting RQs are compared to the Agency's LOCs. LOCs are used by the Agency to indicate when the use of a pesticide, as directed by the label, has the potential to cause adverse effects to non-target organisms.

4.1.1 Risk Quotient Calculations for Aquatic Organisms

There is a potential for exposure of the active ingredient to aquatic organisms (fish and invertebrates); toxicity information is used to estimate the risks to aquatic organisms as a result of surface runoff and spray drift from tebuthiuron uses. The LD_{50} and EC_{50} are used to estimate acute risk for adverse effects on survival to fish and invertebrates, respectively, and the NOAEC is used to estimate chronic risk for adverse effects to both fish and invertebrates. A single application at 4 and 6 lb a.i./A was modeled. Applications from aerial, ground and granular uses were modeled.

Tables 4.1 and 4.2 list acute and chronic RQs calculated for aquatic organisms (freshwater fish also surrogates for aquatic-phase amphibians) exposed to tebuthiuron based on the EECs generated from PRZM-EXAMS modeling.

Results of the assessment on aquatic organisms indicate no acute or chronic LOC exceedances for fish and invertebrates exposed to tebuthiuron (**Table 4.1 –** freshwater fish; **Table 4.2 –** freshwater invertebrates; and **Table 4.3** – estuarine/marine invertebrates); acute and chronic RQs were generally <0.01 and <0.1, respectively. Maximum acute and chronic RQs were 0.02 and 0.2, respectively, using the surrogate scenario of aerial applications in Texas, which exposure from aerial applications is expected to be the highest. Because RQs did not exceeded the LOCs for the Texas scenario with aerial applications, at which exposure is the highest; it is anticipated RQs for ground and granular applications along with the remaining aerial application scenarios modeled to be below the LOCs as well. Acute and chronic RQs for estuarine/marine fish were not calculated since mortality and sub-lethal effects were not established (LC_{50} >98 mg a.i./L; ACR-derived NOAEC >18 mg a.i./L).

For listed species, LOC exceedances require an additional in-depth listed species evaluation of the potential co-occurrence of listed species in tebuthiuron-treated areas to characterize risks. Likewise, the probability of an acute effect (*i.e.*, mortality) to an endangered species based on the acute RQ value was calculated. Based on results, the probability of an acute effect to aquatic animals was minimal (ranges from 1 in 9×10^{18} to 1 in $>3 \times 10^{155}$).

The potential risks to fish and invertebrates are discussed further in **Section 4.2**.

Table 4.1. Risk Quotients for Freshwater Fish

Crop	Scenario	App Rate in lbs a.i./A (Method of Application)	1-in-10-year Peak EEC (mg/L)	Freshwater Fish LC$_{50}$ = 106 mg a.i./L (slope = NA)		1-in-10-year 60-day EEC (mg/L)	Freshwater Fish NOAEC = 9.3 mg a.i./L
				Acute RQs	**Probability of Acute Effect[1] (1 in …)**		**Chronic RQs**
Rangeland/ Pastures	CAalfalfa_WirrigOP	6.0 (Aerial)	0.5	<0.01	>$9x10^{18}$	0.5	<0.1
	MNalfalfaOP		0.56	<0.01	>$9x10^{18}$	0.55	<0.1
	NCalfalfaOP		0.60	<0.01	>$9x10^{18}$	0.60	<0.1
	PAalfalfaOP		0.69	<0.01	>$9x10^{18}$	0.69	<0.1
	TXalfalfaOP		1.1	0.01	$9x10^{18}$	1.1	0.12
	CAalfalfa_WirrigOP	4.0 (Aerial)	0.33	<0.01	>$9x10^{18}$	0.33	<0.1
	MNalfalfaOP		0.37	<0.01	>$9x10^{18}$	0.37	<0.1
	NCalfalfaOP		0.40	<0.01	>$9x10^{18}$	0.40	<0.1
	PAalfalfaOP		0.46	<0.01	>$9x10^{18}$	0.46	<0.1
	TXalfalfaOP		0.74	<0.01	>$9x10^{18}$	0.73	<0.1

Abbreviations: [App.] Application; [NA] Not available
A **bold** cell indicates that the RQ meets or exceeds the aquatic LOC for acute risk to listed species (LOC = 0.05), restricted use (LOC = 0.1), or non-listed species (LOC = 0.5) or chronic risk to listed and non-listed species (LOC=1).
[1] Probability of individual mortality based on actual screening level RQ value for tebuthiuron. A default concentration-response slope value of 4.5 is used to generate the probability value when slope values were not available from the available test data (USEPA 2004).

Table 4.2. Risk Quotients for Freshwater Invertebrates							
Crop	**Scenario**	**App Rate in lbs a.i./A / (Method of Application)**	**1-in-10-year Peak EEC (mg/L)**	**Freshwater Invertebrates** LC_{50} = 297 mg a.i./L (slope = 13.3)		**1-in-10-year 21-day EEC (mg/L)**	**Freshwater Invertebrates** NOAEC = 21.8 mg a.i./L
				Acute RQs	**Probability of Acute Effect[1] (1 in …)**		**Chronic RQs**
Rangeland/ Pastures	CAalfalfa_WirrigOP	6.0 (Aerial)	0.5	<0.01	$>3x10^{155}$	0.5	<0.1
	MNalfalfaOP		0.56	<0.01	$>3x10^{155}$	0.56	<0.1
	NCalfalfaOP		0.60	<0.01	$>3x10^{155}$	0.60	<0.1
	PAalfalfaOP		0.69	<0.01	$>3x10^{155}$	0.69	<0.1
	TXalfalfaOP		1.1	<0.01	$>3x10^{155}$	1.1	<0.1
	CAalfalfa_WirrigOP	4.0 (Aerial)	0.33	<0.01	$>3x10^{155}$	0.33	<0.1
	MNalfalfaOP		0.37	<0.01	$>3x10^{155}$	0.37	<0.1
	NCalfalfaOP		0.40	<0.01	$>3x10^{155}$	0.40	<0.1
	PAalfalfaOP		0.46	<0.01	$>3x10^{155}$	0.46	<0.1
	TXalfalfaOP		0.74	<0.01	$>3x10^{155}$	0.74	<0.1

Abbreviations: [App.] Application.
A **bold** cell indicates that the RQ meets or exceeds the aquatic LOCs.
[1] Probability of individual mortality based on actual screening level RQ value for tebuthiuron. A concentration-response slope value of 13.3 is used to generate the probability value (USEPA 2004).

Table 4.3. Risk Quotients for Estuarine/marine Invertebrates								
Crop	**Scenario**	**App Rate in lbs a.i./A / (Method of Application)**	**1-in-10-year Peak EEC (mg/L)**	**Estuarine/marine Invertebrates** LC$_{50}$ = 62 mg a.i./L (slope = N/A)		**1-in-10-year 21-day EEC (mg/L)**	**Estuarine/ marine Invertebrates** NOAEC = 4.56 mg a.i./L
				Acute RQs	**Probability of Acute Effect[1] (1 in …)**		**Chronic RQs**
Rangeland/ Pastures	CAalfalfa_WirrigOP	6.0 (Aerial)	0.5	<0.01	>9x10^{18}	0.5	0.1
	MNalfalfaOP		0.56	<0.01	>9x10^{18}	0.56	0.1
	NCalfalfaOP		0.60	<0.01	>9x10^{18}	0.60	0.1
	PAalfalfaOP		0.69	0.01	9x10^{18}	0.69	0.2
	TXalfalfaOP		1.1	0.02	10x10^{13}	1.1	0.2
	CAalfalfa_WirrigOP	4.0 (Aerial)	0.33	<0.01	>9x10^{18}	0.33	<0.1
	MNalfalfaOP		0.37	<0.01	>9x10^{18}	0.37	<0.1
	NCalfalfaOP		0.40	<0.01	>9x10^{18}	0.40	<0.1
	PAalfalfaOP		0.46	<0.01	>9x10^{18}	0.46	0.1
	TXalfalfaOP		0.74	0.01	9x10^{18}	0.74	0.2

Abbreviations: App. Application.

A **bold** cell indicates that the RQ meets or exceeds the aquatic LOCs.

[1] Probability of individual mortality based on actual screening level RQ value for tebuthiuron. A default concentration-response slope value of 4.5 is used to generate the probability value when slope values were not available from the available test data (USEPA 2004).

4.1.2 Risk Quotient Calculations for Aquatic Plants

There is a potential for exposure of the active ingredient to aquatic vascular and nonvascular plant species. Toxicity information are used to estimate the risks to aquatic plants as a result of surface runoff and spray drift from broadcast ground applications via spray or granules. The IC_{50} is used to estimate risk for adverse effects on growth to *non-listed* aquatic plants and the NOAEC (or EC_{05} when a NOAEC is not available) is used to estimate risk for adverse effects on growth to *listed* aquatic plants.

According to peak PRZM/EXAMS EECs and the range of application rates for tebuthiuron uses every year and toxicity to aquatic plants, the non-listed and listed RQs for aquatic plants (both vascular and nonvascular species) are above Agency's plant LOC of 1. The RQs were 2-29 for aquatic plants exposed to tebuthiuron uses (**Table 4.4**).

The potential risks to aquatic plants are discussed further in **Section 4.2**.

Table 4.4. Risk Quotients for Aquatic Plants							
Crop	**Scenario**	**App Rate (lbs/A)**	**1-in-10 year Peak EEC[4] (mg/L)**	**Aquatic Vascular Plants** IC_{50} = 0.13 mg a.i./L NOAEC = 0.05 mg a.i./L		**Aquatic Nonvascular Plants** IC_{50} = 0.05 mg a.i./L NOAEC = 0.038 mg a.i./L	
				Non-listed RQs	**Listed RQs**	**Non-listed RQs**	**Listed RQs**
Rangeland / Pastures	CAalfalfa_WirrigOP	6.0 (Aerial)	0.5	**4**	**10**	**10**	**13**
	MNalfalfaOP		0.56	**4**	**11**	**11**	**15**
	NCalfalfaOP		0.60	**5**	**12**	**12**	**16**
	PAalfalfaOP		0.69	**5**	**14**	**14**	**18**
	TXalfalfaOP		1.1	**8**	**22**	**22**	**29**
	CAalfalfa_WirrigOP	4.0 (Aerial)	0.33	**3**	**7**	**7**	**9**
	MNalfalfaOP		0.37	**3**	**7**	**7**	**10**
	NCalfalfaOP		0.40	**3**	**8**	**8**	**11**
	PAalfalfaOP		0.46	**4**	**9**	**9**	**12**
	TXalfalfaOP		0.74	**6**	**15**	**15**	**19**
	CAalfalfa_WirrigOP	6.0 (Ground)	0.37	**3**	**7**	**7**	**10**
	MNalfalfaOP		0.38	**3**	**8**	**8**	**10**
	NCalfalfaOP		0.45	**3**	**9**	**9**	**12**
	PAalfalfaOP		0.53	**4**	**11**	**11**	**14**
	TXalfalfaOP		1.0	**8**	**20**	**20**	**26**
	CAalfalfa_WirrigOP	4.0 (Ground)	0.25	**2**	**5**	**5**	**7**
	MNalfalfaOP		0.25	**2**	**5**	**5**	**7**
	NCalfalfaOP		0.30	**3**	**6**	**6**	**8**
	PAalfalfaOP		0.36	**3**	**7**	**7**	**9**
	TXalfalfaOP		0.68	**5**	**14**	**14**	**18**
	CAalfalfa_WirrigOP	6.0 (Granules)	0.34	**3**	**7**	**7**	**9**
	MNalfalfaOP		0.33	**3**	**7**	**7**	**9**
	NCalfalfaOP		0.41	**3**	**8**	**8**	**11**

Table 4.4. Risk Quotients for Aquatic Plants							
Crop	Scenario	App Rate (lbs/A)	1-in-10 year Peak EEC[4] (mg/L)	Aquatic Vascular Plants IC_{50} = 0.13 mg a.i./L NOAEC = 0.05 mg a.i./L		Aquatic Nonvascular Plants IC_{50} = 0.05 mg a.i./L NOAEC = 0.038 mg a.i./L	
				Non-listed RQs	Listed RQs	Non-listed RQs	Listed RQs
	PAalfalfaOP		0.49	**4**	**10**	**10**	**13**
	TXalfalfaOP		1.0	**8**	**20**	**20**	**26**
	CAalfalfa_WirrigOP	4.0 (Granules)	0.22	**2**	**4**	**4**	**6**
	MNalfalfaOP		0.22	**2**	**4**	**4**	**6**
	NCalfalfaOP		0.28	**2**	**6**	**6**	**7**
	PAalfalfaOP		0.33	**3**	**7**	**7**	**9**
	TXalfalfaOP		0.66	**5**	**13**	**13**	**17**

Abbreviations: [App.] Application

A **bold** cell indicates that the RQ meets or exceeds the LOC for non-listed or listed plants (LOC = 1).

4.1.3. Risk Quotient Calculations for Terrestrial Animals

For this screening-level risk assessment with birds and mammals, acute and chronic RQs are derived based on ecological toxicity data for tebuthiuron, and then directly compared to the dietary-based EECs generated from T-REX. For dose-based RQs, the EECs and toxicity values are first adjusted based on food intake and body weight differences of the terrestrial animals prior to the assessment. Size classes are not used in dietary-based RQs. The LD_{50} and LC_{50} are used to estimate acute risk for adverse effects on survival to both birds and mammals; the NOAEC/NOAEL is used to estimate chronic risk for adverse effects on reproduction and growth to birds and mammals. Dietary-based exposure modeling for granular consumption was not available. Therefore, dietary-based RQs for granular uses could not be calculated; it is presumed the dietary-based RQs for granular uses are equivalent to the RQs for spray uses. Dose-based exposure modeling for granular consumption is available; however, all of the dose-based toxicity values for birds were non-definitive; thus, the dose-based RQs for granular uses were not calculated for birds. On the other hand, the mammal dose-based toxicity value was definitive, and RQs for mammals consuming granules were calculated. The potential risk for granular exposure to birds and mammals is discussed in the Risk Description section.

Similar to aquatic organisms, the probability of an acute effect to terrestrial organisms was estimated for the additional endangered species assessment and is included in the RQ tables below, where applicable. As of a result, the probability of an acute effect to terrestrial animals ranges from negligible (1 in $2x10^{19}$) to absolute certainty (1 in 1).

Birds

There is a potential for acute exposure to birds via the oral route, but acute dose-based RQs were not calculated because definitive toxicity endpoints for upland game bird and waterfowl were not established (mallard and northern quail oral LD_{50s} >2000 mg a.i./kg-bw), and there were difficulties in obtaining a dose-based value for the passerine (*e.g.*, severe regurgitation).

At the maximum application rate of 6 lb a.i./A applied broadcast as a liquid spray, the acute dietary-based RQs of 0.38 – 0.98 for birds based on a LC_{50} of 1465 mg a.i./kg-diet for the zebra finch were 3-10x above the listed species LOC of 0.1, for birds that consume vegetation and insects in tebuthiuron-treated sites **(Table 4.5)**. Only birds consuming fruits/pods/seeds did not exceeded the LOC (Highest RQ = 0.06). There is an uncertainty with the RQs calculated for the bobwhite quail and mallard that exceeded the LOC when the zebra LC_{50} of 1465 mg a.i./kg-diet was used in the calculations. If the toxicity of the upland game bird (LC_{50} >5113 mg a.i./kg diet) or mallard (LC_{50} >5093 mg a.i./kg-diet) was used instead, the acute RQs would be <0.01 or 10x greater than the highest EECs for the mallard and quail species, suggesting the effects to upland game and waterfowl birds would be minimal.

At 4 lb a.i./A applied broadcast as a liquid spray, the acute dietary-based RQs of 0.26-0.66 were 2-7x above the listed species LOC of 0.1 for birds that consume vegetation and insects in tebuthiuron-treated sites **(Table 4.5)**.

As stated above, the dietary-based acute RQs could not be calculated for granular or pellet uses, it is presumed the acute RQs would be the same for liquid sprays if sprayed at 6 or 4 lb a.i./A. Thus, granule uses would be 3-10x above the LOC at 6 lb a.i./A and 2-7x above the LOC at 4 lb a.i./A. This is an uncertainty since the modeling for liquid spraying assumes 100% of the active ingredient when the pelleted and granular formulations actually has only 40% and 5% of tebuthiuron, respectively.

For liquid sprays at 6 lb a.i./A, chronic RQs of 6-14 for birds based upon an NOAEC of 100 mg a.i./kg-diet were 6-14x above the LOC of 1 for potential risk to non-listed and listed birds consuming vegetation and insects with tebuthiuron residues (**Table 4.6**). Only birds consuming fruits/pods/seeds did not exceed the chronic LOC (Highest RQ = 0.9).

For liquid sprays at 4 lb a.i./A, chronic RQs were 4-10 for birds; which is 4 to 10x above the LOC of 1.

No methodology is available to model chronic exposure to birds from granular or pellet uses. Thus it is presumed the chronic RQs for granular uses would be the same of the RQs for liquid sprays which is 6-14x and 4-10x above the chronic LOC for 6 and 4 lb a.i./A, respectively.

The potential for risk to birds is discussed in the Risk Description section.

Table 4.5. Acute Avian Dietary-Based Risk Quotients																
Site	LC_{50} (mg a.i./kg-diet)	EECs and RQs														
		Short Grass			Tall Grass			Broadleaf Plants			Fruits/Pods/Seeds			Arthropods		
		EEC	RQ	IEC[3]	EEC	RQ	IEC	EEC	RQ	IEC	EEC	RQ	IEC	EEC	RQ	IEC
Rangeland[1]	1465	1440	**0.98**	2.1	660	**0.45**	83	810	**0.55**	22	90	0.06	$1x10^{15}$	564	**0.38**	317
Rangeland[2]	1465	960	**0.66**	8.3	440	**0.30**	2950	540	**0.37**	400	60	0.04	$2x10^{19}$	376	**0.26**	$1x10^{04}$

Size class not used for dietary risk quotients
Bold values indicate terrestrial LOC exceedances for acute risk to listed species (LOC = 0.1), restricted use (LOC = 0.2), or non-listed species (LOC = 0.5) or chronic risk to listed and non-listed species (LOC=1).
[1] Exposure scenario based on 1 broadcast spray at 6 lb a.i./A
[2] Exposure scenario based on 1 broadcast spray at 4 lb a.i./A
[3] Probability of individual mortality based on actual screening level RQ value for tebuthiuron (1 in ....). A concentration-response slope value of 6.5 is used to generate the probability value (USEPA 2004).

Table 4.6. Chronic Avian Dietary-Based Risk Quotients											
Site	NOAEC (mg a.i./kg-diet)	EECs and RQs									
		Short Grass		Tall Grass		Broadleaf Plants		Fruits/Pods/Seeds		Arthropods	
		EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
Rangeland[1]	100	1440	**14**	660	**7**	810	**8**	90	0.9	564	**6**
Rangeland[2]	100	960	**10**	440	**4**	540	**5**	60	0.6	376	**4**

Size class not used for dietary risk quotients
Bold values indicate LOC exceedances (exceeds the LOC of 1 for chronic risk)
[1] Exposure scenario based on 1 broadcast spray at 6 lb a.i./A
[2] Exposure scenario based on 1 broadcast spray at 4 lb a.i./A

Terrestrial-phase Amphibians and Reptiles

EFED currently uses surrogate data (birds) for terrestrial-phase amphibians and reptiles when data are not available. There were LOC exceedances for birds; these exceedances apply to terrestrial-phase amphibian and reptiles. Risks are discussed in the Risk Description section.

Mammals

Acute dose-based RQ values of 0.19-1.6 for mammals based on toxicity data for the laboratory rat (female LD_{50} = 385 mg a.i./kg-bw) were above the LOC for mammals that eat vegetation and insects exposed to tebuthiuron from ground or aerial applications at 4 and 6 lb a.i./A (**Table 4.7**). These RQs were 2-16x higher than the listed species LOC of 0.1 and 3x higher than the non-listed species LOC of 0.5. The RQ of 0.1 was at the LOC for 15-g mammals that consume fruits/pods/seeds for the 6 lb a.i./A application scenario. RQs for 35-g and 1000-g mammals that consume fruits/pods/seeds for the 6 lb a.i./A application and for 15-g mammals that eat fruits/pods/seeds for the 4 lb a.i./A application were not above the acute listed LOC (Highest RQ = 0.09). RQs for granivorous mammals that eat grain and seeds were not above the LOC (Highest RQ = 0.02).

For granular and pellet consumption, RQs for 15-g and 35-g mammals exceeded the acute LOCs, while the RQs for 1000-g mammals do not exceeded the LOCs. However, for granular uses at 4 lb a.i./A, the RQ of 0.09 for 35-g mammals does not exceed the acute listed species LOC of 0.1. The RQs that exceeded the listed species LOC of 0.1 ranged from 0.13 to 1.96, which were 1 to 19x higher than the listed species LOC.

The probability for an acute effect to 15-g mammals that consume tebuthiuron-exposed short grass, using the highest application scenario, at 6 lb a.i./A with broadcast liquid sprays is 1 in 1.22; for 35-g mammals, it is 1 in 1.34; and for 1000-g mammal it is 1 in 4. **Table 4.7** provides more details on the probability of an acute effect to 15-g, 35-g, 1000-g mammals that consume these selected feed items treated with tebuthiuron. For pellet uses at 6 lb a.i./A with 40% of tebuthiuron in the formulation, the probability for an acute effect to 15-g mammals is 1 in 1.1; for 35-g mammals, it is 1 in 1.88; and for 1000-g mammals it is 1 in $3x10^6$. For granular applications at 6 and 4 lb a.i./A with 5% of tebuthiuron in its formulation, the probability to 15-g mammals is 1 in 378 and 1 in 5850, respectively.

Table 4.7. Acute Mammalian Dose-Based Risk Quotients

Site	Size Class (grams)	Adjusted[7] LD_{50}	EECs and RQs for Spray Uses								
			Short Grass			Tall Grass			Broadleaf Plants		
			EEC[7]	RQ	IEC (1 in ..)[9]	EEC	RQ	IEC (1 in ..)	EEC	RQ	IEC (1 in ..)
Rangeland (6 lb/A broadcast spray) [1]	15	851.66	1373	**1.6**	1.22	629	**0.74**	4	772	**0.91**	2
	35	689.08	949	**1.4**	1.34	435	**0.64**	5	534	**0.78**	3
	1000	298.05	220	**0.7**	4	101	**0.34**	57	124	**0.42**	22
Rangeland (4 lb/A broadcast spray) [2]	15	851.66	915	**1.1**	1.74	420	**0.50**	11	515	**0.61**	6
	35	689.08	633	**0.9**	2	290	**0.42**	22	356	**0.52**	10
	1000	298.05	147	**0.5**	11	67	**0.23**	491	83	**0.28**	156
Site	**Size Class (grams)**	**Adjusted[7] LD_{50}**	**EECs and RQs for Spray Uses**								
			Fruits/Pods/ Seeds			**Arthropods**			**Granivore**		
			EEC	**RQ**	**IEC (1 in ..)**	**EEC**	**RQ**	**IEC (1 in ..)**	**EEC**	**RQ**	**IEC (1 in ..)**
Rangeland (6 lb/A broadcast spray) [1]	15	851.66	86	**0.10**	$3x10^{5}$	538	**0.64**	5	19	0.02	$10x10^{13}$
	35	689.08	59	0.09	$8x10^{5}$	372	**0.54**	9	13	0.02	$10x10^{13}$
	1000	298.05	14	0.05	$4x10^{8}$	86	**0.29**	129	3	0.01	$9x10^{18}$
Rangeland (4 lb/A broadcast spray) [2]	15	851.66	57	0.07	$10x10^{6}$	358	**0.42**	22	13	0.02	$10x10^{13}$
	35	689.08	40	0.06	$5x10^{7}$	248	**0.36**	44	8.8	0.01	$9x10^{18}$
	1000	298.05	9	0.03	$3x10^{11}$	57	**0.19**	1710	2.1	<0.01	$>9x10^{18}$
Site	**Size Class (grams)**	**Adjusted[7] LD_{50}**	**EECs and RQs for Granular Uses**								
			EEC[8]	**RQ**	**IEC (1 in ..)**						
Rangeland (6 lb/A pellet broadcast) [3]	15	851.66	25	**1.96**	1.1						
	35	689.08	25	**1.04**	1.88						
	1000	298.05	25	0.08	$3x10^{6}$						
Rangeland (4 lb/A pellet broadcast) [4]	15	851.66	16.7	**1.31**	1.43						
	35	689.08	16.7	**0.69**	4.27						
	1000	298.05	16.7	0.06	$5x10^{7}$						
Rangeland (6 lb/A granular broadcast) [5]	15	851.66	3.12	**0.24**	378						
	35	689.08	3.12	**0.13**	$3x10^{4}$						
	1000	298.05	3.12	0.01	$9x10^{18}$						
Rangeland (4 lb/A granular broadcast) [6]	15	851.66	2.08	**0.16**	5850						
	35	689.08	2.08	0.09	$8x10^{5}$						
	1000	298.05	2.08	0.01	$6x10^{21}$						

Bold values indicate terrestrial LOC exceedances

[1] Exposure scenario based on 1 broadcast spray at 6 lb a.i./A
[2] Exposure scenario based on 1 broadcast spray at 4 lb a.i./A
[3] Exposure scenario based on 1 broadcast pellet application at 6 lb a.i./A with 40% of tebuthiuron
[4] Exposure scenario based on 1 broadcast pellet application at 4 lb a.i./A with 40% of tebuthiuron
[5] Exposure scenario based on 1 broadcast granular application at 6 lb a.i./A with 5% of tebuthiuron
[6] Exposure scenario based on 1 broadcast granular application at 4 lb a.i./A with 5% of tebuthiuron
[7] mg a.i./kg-bw
[8] mg a.i./ft^2
[9] Probability of individual mortality based on actual screening level RQ value for tebuthiuron. A default concentration-response slope value of 4.5 is used to generate the probability value when slope values were not available from the available test data (IEC model V.1.1 USEPA 2004).

Chronic RQ values for mammals are presented in **Tables 4.8 and 4.9.** Based on the rat chronic NOAEL of 14 mg a.i./kg-bw/day (200 mg/kg-diet) for exposure to tebuthiuron, both dietary and dose-based RQ values exceed the chronic risk LOC (LOC = 1) for all size classes of mammals that consume short grass, tall grass, broadleaf plants, fruits and pods (dose-based only), and arthropods (RQs ranged 1.9-45). These chronic RQs were 2-45x higher than the chronic LOC of 1.0. Chronic dietary-based RQs for applications of 4 and 6 lb a.i/A tebuthiuron do not exceed the chronic risk LOC for mammals consuming fruits/pods/seeds (Highest RQ = 0.45). Chronic dose-based RQs do not exceed the chronic risk LOC for all size classes of mammals that consume seeds (Highest RQ = 0.62) and 1000 g mammals that consume fruits/pods/seeds (Highest RQ = 0.85).

Chronic RQs for granular and pelleted formulations are not calculated.

The potential for risk to mammals is further discussed in the Risk Description section.

Table 4.8. Chronic Mammalian Dietary-Based Risk Quotients

Site	NOAEL (mg a.i./kg-diet)	EECs and RQs									
		Short Grass		Tall Grass		Broadleaf Plants		Fruits/Pods/ Seeds		Arthropods	
		EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
Rangeland [1]	200	1440	**7.2**	660	**3.3**	810	**4.1**	90	0.45	564	**2.8**
Rangeland [2]	200	960	**4.8**	440	**2.2**	540	**2.7**	60	0.30	376	**1.9**

Size class not used for dietary risk quotients
Bold values indicate LOC exceedances (exceeds the LOC of 1 for chronic risk)
[1] Exposure scenario based on 1 broadcast spray at 6 lb a.i./A
[2] Exposure scenario based on 1 broadcast spray at 4 lb a.i./A

Table 4.9. Chronic Mammalian Dose-Based Risk Quotients															
Site	Size Class (grams)	Adjusted NOAEL	EECs and RQs												
			Short Grass		Tall Grass		Broadleaf Plants		Fruits/Pods/ Seeds		Arthropods		Granivore		
			EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	
Rangeland [1]	15	30.77	1373	**45**	629	**20**	773	**25**	86	**3**	538	**17**	19	0.6	
	35	24.90	949	**38**	435	**17**	534	**21**	59	**2**	372	**15**	13	0.5	
	1000	10.77	220	**20**	101	**9**	124	**11**	14	**1**	86	**8**	3	0.3	
Rangeland [2]	15	30.77	915	**30**	420	**14**	515	**17**	57	**2**	358	**12**	13	0.4	
	35	24.90	633	**25**	290	**12**	356	**14**	40	**2**	248	**10**	9	0.4	
	1000	10.77	147	**14**	67	**6**	83	**8**	9	0.9	57	**5**	2	0.2	

Bold values indicate LOC exceedances (exceeds the LOC of 1 for chronic risk)

[1] Exposure scenario based on 1 broadcast spray at 6 lb a.i./A

[2] Exposure scenario based on 1 broadcast spray at 4 lb a.i./A

Beneficial Insects

Tebuthiuron is classified as "practically nontoxic" to non-target beneficial insects including honeybees (honeybee acute contact LD_{50} >100 µg a.i./bee) on an acute exposure basis. The need for precautionary label language for beneficial insects is not required and is discussed further in the Risk Description section.

Terrestrial Invertebrates

EFED currently uses surrogate data (bees) for terrestrial invertebrates when data are not available. There is a potential for acute exposure to terrestrial invertebrates, but acute RQs were not calculated because tebuthiuron toxicity information for the honeybee was not established (honeybee acute contact LD_{50s} >100 µg a.i./bee). Risks to terrestrial invertebrates are discussed in the Risk Description section.

4.1.4. Risk Quotient Calculations for Terrestrial Plants in Terrestrial and Semi-aquatic Environments

For this risk assessment with terrestrial monocots and dicots, non-listed and listed plant species RQs are derived based on ecological toxicity data for the active ingredient and then compared to TerrPlant EECs for plants in non-target area receiving surface runoff combined with spray drift adjacent to the target area. Details of the TerrPlant model and EECs are presented in **Table 2.11**.

There is a potential for exposure of tebuthiuron to terrestrial plants. Toxicity information on the TEP (Typical End-use Product) are used to estimate the risks to non-target terrestrial plants inhabiting dry or semi-aquatic areas adjacent to a treated field as a result of surface runoff and/or spray drift. The EC_{25} was used to estimate risk for adverse effects on growth to *non-listed* plant species while the NOAEC (or EC_{05} when a NOAEC is not available) was used to estimate risk for adverse effects on growth to *listed* plant species. Note: TerrPlant does not consider exposures to plants from multiple pesticide applications; thus, results are based on single pesticide applications.

Table 4.10 presents RQs for exposure of terrestrial plants to tebuthiuron via ground and aerial spray applications as well as granular applications.

RQs (1.11-1031) for *non-listed* and *listed* monocots and dicots inhabiting dry and semi-aquatic areas adjacent to a treated site exposed to tebuthiuron through a combination of surface water runoff and spray drift exceed the plant LOC of 1.0 for broadcast applications by aerial, ground, and granular at 4 and 6 lb a.i./A. However, when reduced to 4 lb a.i./A from 6 lb a.i./A, *non-listed* and *listed* monocots inhabiting dry areas adjacent to a treated site exposed to tebuthiuron through runoff and drift via ground or granular applications were no longer above the LOC of 1.0; the highest RQ was 0.96.

There is no LOC exceedance for *non-listed* and *listed* monocots exposed to drift alone from aerial uses at 4 lb a.i./A tebuthiuron or from ground or granular applications at 4 and 6 lb a.i./A tebuthiuron; the highest RQ is 0.74.

For granular uses, no drift is produced; thus, there are no exceedances for *non-listed* and *listed* plants exposed to spray drift alone.

The potential risks to terrestrial plants are discussed further in the Risk Description section.

Table 4.10. Terrestrial Plant Risk Quotient [1, 2, 3, 4]						
Scenario	**Non-listed RQs**			**Listed RQs**		
	Terrestrial Adjacent area	**Semi-aquatic Adjacent Area**	**Drift**	**Terrestrial Adjacent area**	**Semi-aquatic Adjacent Area**	**Drift**
One Aerial Spray at 6 lb a.i./A						
Monocot	**2.22**	**12.2**	**1.11**	**2.4**	**13.2**	**1.2**
Dicot	**33.3**	**183**	**16.7**	**188**	**1031**	**94**
One Aerial Spray at 4 lb a.i./A						
Monocot	**1.48**	**8.15**	0.74	**1.6**	**8.8**	0.8
Dicot	**22.2**	**122**	**11.1**	**125**	**688**	**62.5**
One Ground Spray at 6 lb a.i./A						
Monocot	**1.3**	**11.3**	0.22	**1.4**	**12.2**	0.24
Dicot	**20**	**170**	**3.3**	**113**	**956**	**18.8**
One Ground Spray at 4 lb a.i./A						
Monocot	0.89	**7.56**	0.15	0.96	**8.16**	0.16
Dicot	**13.3**	**113**	**2.22**	**75**	**638**	**12.5**
One Granular Application at 6 lb a.i./A						
Monocot	**1.11**	**11.1**	N/A	**1.2**	**12**	N/A
Dicot	**16.67**	**167**	N/A	**94**	**938**	N/A
One Granular Application at 4 lb a.i./A						
Monocot	0.74	**7.41**	N/A	0.8	**8**	N/A
Dicot	**11.1**	**111**	N/A	**62.5**	**625**	N/A

[1] RQs for aerial and ground spray and granular applications in this table were calculated using the maximum application rates for tebuthiuron uses.
[2] Non-listed toxicity thresholds (EC_{25}) were 0.27, 0.018, 0.3, and 0.16 lb a.i./A for seedling emergence monocot, seedling emergence dicot, vegetative vigor monocot, and vegetative vigor dicot.
[3] Corresponding listed toxicity thresholds (NOAEC) were 0.25, 0.0032, 0.12, and 0.62 lb a.i./A for seedling emergence monocot, seedling emergence dicot, vegetative vigor monocot, and vegetative vigor dicot.
[4] Values in bold are LOC exceedances (Exceeds the LOC of 1 for potential risk to non-listed and listed plant species).

4.2. Risk Description

The risk hypothesis states that the use of tebuthiuron as an herbicide for terrestrial crop sites has the potential to adversely affect survival, reproduction, and/or growth of non-target aquatic and terrestrial animals and plants, including Federally-listed endangered and threatened species. Based on the available ecotoxicity data and predicted environmental exposures, the hypothesis is confirmed for potential adverse effects to birds, terrestrial-phase amphibians, reptiles, mammals, terrestrial plants, terrestrial invertebrates and aquatic plants (vascular and algae/diatoms) based on the registered uses for tebuthiuron. Results of the risk estimation indicate aquatic animals are not expected to be affected. Label protections for beneficial insects are not required. The following sections discuss the potential risks of tebuthiuron to these taxonomic groups.

4.2.1. Risks to Aquatic Animals and Plants

In the conceptual model, spray drift and surface runoff/leaching to adjacent bodies of water were predicted as the most likely sources of exposure of tebuthiuron to non-target aquatic organisms and plants. Risks to aquatic species (*i.e.*, fish, invertebrates, and plants) were assessed based on modeled estimated environmental concentrations (EECs) and available toxicity data. The aquatic EECs for the ecological exposure to the TGAI were estimated using the PRZM/EXAMS model to evaluate whether the potential for exposure is nationwide or limited to certain locations (**Table 3.8**).

Risk to Aquatic Organisms

Available acute toxicity data indicates that tebuthiuron is practically non-toxic to fish and generally practically non-toxic to invertebrates on an acute basis. The pink shrimp was the only aquatic animal to show slight sensitivity to tebuthiuron. The other invertebrates exposed to tebuthiuron were the daphnid, fiddler crab, and oyster bivalve; none of them were affected up to the highest concentration tested. The acute endpoint for pink shrimp, the most sensitive aquatic animal from the available studies, was compared to PRZM/EXAMS peak EECs for non-target fish and invertebrates inhabiting waterbodies adjacent to fields applied with tebuthiuron. The highest acute RQ was 0.02, which did not exceed the Agency's endangered species LOC of 0.05. With a maximum RQ of 0.02 for acute effects to aquatic animals, the probability for acute effect is 1 in 9×10^{18} or lower.

The lowest test level of no observed adverse reproduction effects for aquatic animals (*i.e.*, 9.3 mg a.i./L based on reduced length in fathead minnow) was compared to PRZM/EXAMS 60-day EECs for non-target organism exposed to tebuthiuron as a result of surface water runoff and spray drift. The highest chronic RQ was 0.2, which is below the chronic LOC of 1.0. Aquatic animals, including aquatic-phase amphibians for which freshwater fish served as a surrogate, are not anticipated to be at risk for adverse effects on survival, reproduction, and growth when exposed to tebuthiuron.

Bluegills exposed to tebuthiuron concentrations of 5.0 ppm demonstrated bioconcentration factors of 1.98, 3.40, and 2.63 for edible tissue, nonedible tissue, and whole fish, respectively. Accumulated residues depurated rapidly from fish tissue with depuration half-lives of 0.33 and 0.51 days reported for edible and nonedible tissue, respectively, which indicates tebuthiuron is not expected to bioaccumulate in fish. An assessment using the Agency's KABAM (KOW (based) Aquatic BioAccumulation Model) v1.0 model was not conducted since both the environmental properties of tebuthiuron and results of bioconcentration studies indicated bioaccumulation in fish and biomagnification through the food chain is unlikely.

Risk to Aquatic Vascular and Non-Vascular Plants

The most sensitive EC_{50}'s derived from the duckweed (*Lemna gibba*) study for aquatic vascular plants and from available studies for aquatic non-vascular plants (marine diatom) were compared to EECs from several PRZM/EXAMs exposure scenarios for non-target, non-listed plants inhabiting bodies of water adjacent to fields treated with tebuthiuron. Non-listed plant RQs for aquatic vascular and non-vascular plants exceeded the non-listed plant species LOC of 1 following one broadcast application of tebuthiuron at 4 and 6 lb a.i./A (RQs = 2-22).

The corresponding NOAECs derived from the duckweed study for aquatic vascular plants and from the marine diatom study for aquatic non-vascular plants were compared to several PRZM/EXAMs exposure scenarios for non-target Federally-listed plants inhabiting bodies of water adjacent to fields treated with tebuthiuron. Listed plant RQs for aquatic vascular and non-vascular plants all exceeded the listed plant species LOC of 1 for tebuthiuron uses (RQs = 4-29).

To assess the range of sensitivity in aquatic non-vascular plant species when exposed to tebuthiuron, a comparison of the least sensitive species (blue-green algae EC_{50} of 0.81 mg a.i./L) and the most conservative PRZM/EXAMS EEC using the TX alfalfa scenario (1.1 mg a.i./L) yields an RQ of 1.4 which does exceed the plant LOC of 1.0. Thus it is anticipated that all algae would be adversely affected when exposed to tebuthiuron. Aquatic vascular plant data were limited to the duckweed study; therefore, the range of sensitivity in aquatic vascular plants adversely affected by tebuthiuron applications could not be assessed.

In addition, the labels state that tebuthiuron is a thiadiazolylurea herbicide that is readily absorbed through the roots and translocated. Once it enters the plant, it acts by inhibiting photosynthesis in the plant. Thus, some herbicidal effects to aquatic plants are anticipated.

The AgDRIFT spray drift model was used to assess the distance from the edge of a site at which RQs for spray drift fall below the aquatic plant LOC of 1 (**Table 4.11**). The RQs were calculated by comparing the amount of deposition at a specific distance (EEC) and the toxicity endpoints for duckweed and marine diatom (EC_{50}). As the distance increases, the chance for exposure to non-target species outside a treated site increases. This spray drift exposure analysis indicates that when aerial-based application methods are used (which produces the highest exposures) at the maximum label rate, exposure falls below the LOC for the most sensitive aquatic vascular and non-vascular plants at 0 and 10 feet, respectively, off-site. At 4 lb a.i./A, there were no LOC exceedances from spray drift exposures via aerial or ground application for aquatic plants inhabiting waterbodies (e.g. pond) adjacent to the edge of a site. Therefore, adverse effects to non-target aquatic plants in waterbodies adjacent to treated site exposed to spray drift alone at or greater than 10 feet are not likely. This suggest aquatic plants inhabiting water bodies adjacent to treated sites subjected to surface water runoff with tebuthiuron residues would more likely be adversely affected than when exposed to off-site spray drift alone.

Table 4.11. Spray Drift (Aquatic) Assessment for Non-Target Listed and Non-Listed Aquatic Vascular and Non-Vascular Plant Species						
No. of Applications and Application Rate (lb a.i./A)	**Distance from Edge of Field**	**% of Application Rate**	**EEC (mg a.i./L)**	**Non-listed Plant RQ (EEC/EC_{50})**	**Listed Plant RQ (EEC/ NOAEC)**	**Spray Method**
Aquatic vascular plants inhabiting pond [a]						
1 @ 6	0 feet	13	0.04	0.3	0.8	Aerial
Aquatic non-vascular plants inhabiting pond [b]						
1 @ 6	0 feet	13	0.04	0.8	**1**	Aerial
1 @ 6	10 feet	11	0.036	0.7	0.95	
1 @ 6	0 feet	2.7	0.009	0.2	0.2	Ground
1 @ 6	10 feet	1.4	0.005	0.1	0.1	
1 @ 4	0 feet	13	0.03	0.6	0.8	Aerial
1 @ 4	10 feet	11	0.024	0.5	0.6	
1 @ 4	0 feet	2.7	0.006	0.1	0.2	Ground
1 @ 4	10 feet	1.4	0.003	0.06	0.08	

[a] Based on duckweed EC_{50} of 0.13 mg a.i./L and NOAEC of 0.05 mg a.i./L. (MRID #41080404)
[b] Based on marine diatom EC_{50} and NOAEC of 0.05 and 0.038 mg a.i./L, respectively. (MRID #41080402)
*Value in bold indicates the LOC (=1) is exceeded.

4.2.2. Risks to Terrestrial Animals and Plants

In the conceptual model, dietary ingestion of tebuthiuron residues on vegetative matter, insects and granules on treated areas are predicted as the most likely sources of tebuthiuron exposure to terrestrial animals. Spray drift, runoff and wind erosion of soil particles with resulting residues on upland and/or wetland foliage and soil are the most likely sources of tebuthiuron exposure to non-target terrestrial plants, including Federally-listed endangered and threatened species. Risks to terrestrial species (*i.e.*, birds, mammals and plants) are assessed based on modeled estimated environmental concentrations (EECs) and available toxicity data. Terrestrial EECs for ecological exposure to the TGAI are estimated using T-REX (**Tables 3.9, 3.10, and 3.11**) and TerrPlant (**Table 3.12**).

Risk to Terrestrial Animals

Available avian acute toxicity data indicate that tebuthiuron is practically non-toxic to upland game birds and waterfowl on an acute basis for both oral and dietary routes (*e.g.*, >2000 mg a.i./kg bw and >5113 mg a.i./kg diet). However, the TGAI is slightly toxic to passerine birds via the dietary route; the dietary-based LC_{50} for passerines is 1465 mg a.i./kg diet as a result of counting extremely low food consumption as mortalities since the birds would not survive throughout the test, including those birds that died. Dietary-based risk quotient calculations focusing on the most conservative T-REX scenario using the short grass EEC of 1440 mg a.i./kg diet was 10 times higher than EPA's LOC of 0.1 for potential risk to Federally-listed endangered and threatened birds and 2 times higher than EPA's LOC of 0.5 for potential risk to non-listed birds. Using the maximum RQ of 0.98 for short grass based upon a broadcast application of 6 lb a.i./A and 20 g birds, this indicates 1 in 2 small-sized birds that consume tebuthiuron-treated short grass would be affected. At 4 lb a.i./A of the same scenario with highest RQ at 0.66, 1 in 8.3 small-sized birds would be affected.

Meanwhile, since dietary concentrations that caused no mortality or acute sub-lethal effects in bobwhite quail and mallard are 3.5x environmentally relevant concentrations, acute risk to upland and waterfowl birds is anticipated to be low.

Chronic avian RQs for ground spray of tebuthiuron were above the chronic risk LOC of 1, with a calculated maximum RQ of 14.4.

Acute and chronic RQs for granular and pellet applications were not available. All acute dose-based endpoints were non-definitive and tools to model chronic EECs were not available in this screening-level assessment; thus, the RQs for granular/pellet and spray uses were assumed equivalent. However, an uncertainty is introduced since this assumption is that all formulations are 100% tebuthiuron. With granular and pelleted formulations containing up to 5% and 40% of tebuthiuron, respectively, it is uncertain the RQs for granular and pellet uses are as high as the spray uses.

No mortalities were observed in the acute studies with the upland game bird and waterfowl, yet significant sub-lethal effects were observed in the reproduction studies at 500 mg a.i./kg diet and higher. These same large birds demonstrated no regurgitation or food avoidance of the test material in the acute oral studies. On the other hand, smaller birds such as passerines were more acutely sensitive to tebuthiuron due to severe regurgitation and extreme food avoidance, which these observations were counted as mortalities in the dietary study. This suggests the acute effects of tebuthiuron may be observed more often in smaller birds compared to larger birds when exposed to tebuthiuron. While chronic reproduction effects were not evaluated for small birds (*i.e.*, passerines), as growth and reproduction (chronic) effects were observed in other avian species, chronic effects could be anticipated in several bird class sizes.

Available mammalian acute toxicity data indicate that tebuthiuron is moderately toxic to mammals on an acute oral basis. Dose-based RQ calculations focusing on the most conservative T-REX scenario indicate that the short grass EEC of 1440 mg a.i./kg diet is 16 times higher than EPA's LOC of 0.1 for potential risk to Federally-listed endangered and threatened mammals and 3 times higher than EPA's LOC of 0.5 for potential risk to non-listed mammals. In addition, rabbits are slightly more acutely sensitive to tebuthiuron than rats; RQs calculated using the rabbit toxicity endpoint would be more than 16 times higher than the LOC. These acute LOC exceedances indicate mammals may be at risk for adverse effects on survival from exposure to tebuthiuron. Using the maximum RQ of 1.6 for short grass and 15 g mammals, 1 in 1.22 small-sized mammals that consume tebuthiuron-treated short grass would be affected. A maximum RQ of 4.9 for granules and 15 g mammals indicates that 1 in 1 small-sized mammals that consume granules would be affected.

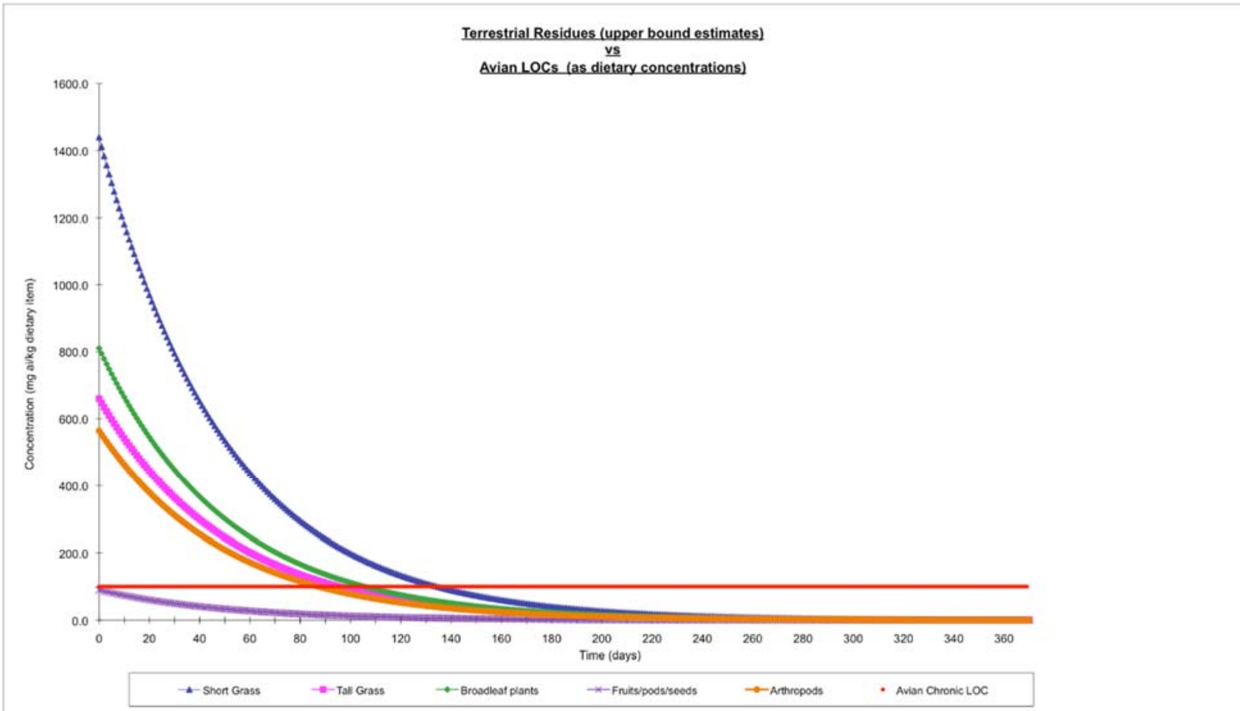
Based on the most sensitive mammalian 2-generation NOAEL and upper bound T-REX EECs, the dose-based RQs of 13-45 exceed the chronic LOC for 15 g, 35 g and 1000 g mammals foraging on short grass, tall grass, broadleaves and arthropods following one tebuthiuron application at 4 or

6 lb a.i./A. For the dietary-based risk estimations, the results were similar; however, there were no LOC exceedances for mammals foraging on fruits/seeds/pods (highest RQ = 0.45). Thus, these exceedances indicate mammals may be at potential risk for adverse effects on reproduction and growth from exposure to tebuthiuron as a result of the labeled uses of the herbicide.

Those adverse effects discussed above would be observed for those terrestrial vertebrates that remain in a tebuthiuron-treated site all the time. The less amount of time a bird or mammal remains in the treated site, the less the risk to terrestrial vertebrates. Also, the smaller the application site (*i.e.* driveway vs. agricultural field) is, the less chance for terrestrial vertebrates to be at risk.

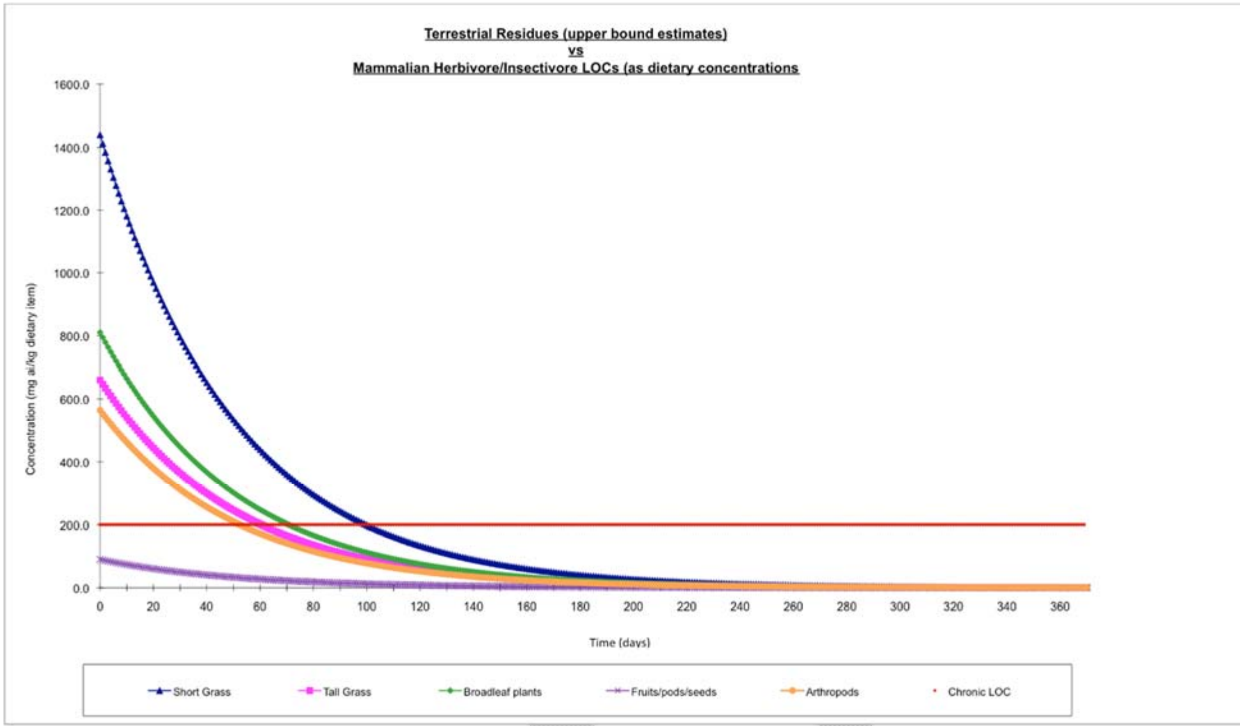
Considering the maximum single tebuthiuron application at 6.0 lbs a.i./A, the potential for adversely affecting the reproduction and growth of terrestrial animals in treated sites is likely. Reducing the application rate would mitigate risks to birds and mammals residing inside the treated site. A reduced application rate that would not result in an acute LOC exceedance for birds would be 0.35 lb a.i./A. For mammals, it would be 0.14 lb a.i./A. At 6.0 lbs a.i./A, the mitigated applications for birds and mammals need to be reduced 17x and 40x, respectively, of the maximum application rate. Using the maximum application rate as an example, **Graphs 4-1 and 4-2** illustrate the days needed to exceed the chronic LOC for adverse effects to birds and mammals, respectively, foraging on food resources in fields/sites treated with tebuthiuron.

Graph 4-1 below illustrates one tebuthiuron application at the maximum application rate of 6.0 lb a.i./A applied as a broadcast application to selected feed items that terrestrial vertebrates rely as a food resource.. Pictured are the EECs for short grass, tall grass, broadleaf plants, fruits/pods/seeds, and arthropods following one application of tebuthiuron. Based on the graph, the upper-bound Kenaga dietary-based EECs exceed the LOC of 1 (NOAEC = 100 mg a.i./kg diet) for birds foraging in tebuthiuron-treated sites following application. Likewise, the number of days in exceedance of the LOC for reproduction and growth effects to birds that forage on vegetation in tebuthiuron-treated sites lasts approximately 80-140 days, the longest when foraging on short grass. Arthropods covered with tebuthiuron residues may be toxic to birds for 55 days. T-REX provides graphs for dietary-based assessments only; graphs for dose-based assessments are not available.



Graph 4-1. Number of applications and days needed to exceed the LOC of 1 for adverse effects of growth and reproduction to <u>birds</u> following tebuthiuron application at 6 lb/A on rangeland and pastures as per label directions.

In **Graph 4-2**, the upper-bound Kenaga dietary-based EECs exceed the LOC of 1 (NOAEC = 200 mg a.i./kg diet) for mammals foraging in tebuthiuron-treated sites following application. Likewise, the number of days in exceedance of the LOC for reproduction and growth effects to mammals that forage on short grass, broadleaves, tall grass, and arthropods in tebuthiuron-treated sites lasts approximately 100, 75, 60, and 50 days, respectively.



Graph 4-2. Number of applications and days needed to exceed the LOC of 1 for adverse effects of growth and reproduction to <u>mammals</u> following tebuthiuron application at 6 lb/A on rangeland and pastures as per label directions.

AgDRIFT was used to assess whether the LOC exceedances should apply to non-target birds and mammals that inhabits areas outside tebuthiuron-treated sites. **Table 4.12** shows the spray drift distances estimated using LOCs divided by risk quotients (calculated based on a single application) as the "Fraction of Applied" in AgDRIFT to estimate the spray drift distance for terrestrial animals. The spray drift exposure analysis indicates that for aerial-based applications, the RQ falls below the LOC for the non-listed bird and mammal at 138 and 479 feet, respectively, off-site. For ground-based applications, the RQ falls below the LOC for bird and mammal at 39 and 125 feet, respectively. This suggests that effects to non-target terrestrial vertebrates could occur outside the site of application.

Table 4.12. Spray Drift (Terrestrial) Assessment for Non-Listed Terrestrial Vertebrate Species Exposed to 6 lb a.i./A Tebuthiuron					
Taxa	**Type of Endpoint**	**Highest Risk Quotient**	**LOC***	**Fraction of Applied (LOC/RQ)**	**Distance from Edge of Field Where RQ Falls below LOC**
Aerial Applications					
Birds	Acute	0.98	0.5	0.51	0 feet
	Chronic	14	1	0.07	138 feet
Mammals	Acute	1.6	0.5	0.3	16 feet
	Chronic	45	1	0.02	479 feet
Ground applications					
Birds	Acute	0.98	0.5	0.51	7 feet
	Chronic	14	1	0.07	39 feet
Mammals	Acute	1.6	0.5	0.3	10 feet
	Chronic	45	1	0.02	125 feet

* The LOCs shown are for non-listed species.

Risk to Terrestrial Monocots and Dicots

Based on the available data, monocots are less sensitive to tebuthiuron than dicots. The RQs for runoff to semi-aquatic areas result in the highest RQs compared to dry areas. This scenario represents a 10 acre area running off into a one acre area. The highest RQ for a combination of runoff and spray drift to semi-aquatic areas is 1031, which exceeds the Agency's LOC of 1 for potential risk to plants. Since the herbicide is absorbed through the roots and translocated throughout, the plant the LOC exceedance for potential risk to non-listed and listed plants inhabiting semi-aquatic areas cannot be discounted.

AgDRIFT was used to assess whether the LOC exceedances should apply to non-target terrestrial plants in dry (**Table 4.13**) and semi-aquatic (**Table 4.14**) areas adjacent to tebuthiuron-treated sites. The spray drift exposure analysis indicates that for aerial-based applications, exposure falls below the LOC for non-listed and listed terrestrial plant exposed to tebuthiuron as a result of spray drift at and greater than 997 feet off-site. However, for ground-based applications, exposure falls below the LOC at approximately 500 and >997 feet for non-listed and listed plants, respectively. This suggests that effects to non-target terrestrial plants could occur outside the site of application.

In addition to the AgDRIFT assessment using the most sensitive plant species, an assessment was conducted on the least sensitive plant species and the highest exposure scenario to observe whether all or some terrestrial plants would be affected when exposed. Corn was used as the least sensitive species with seedling emergence EC_{25} and NOAEC values of 3.1 and 2.0 lb a.i./A, respectively. For plants inhabiting dry area adjacent a treated site, AgDRIFT indicates exposure to drift from aerial and ground broadcast applications using the corn EC_{25} and NOAEC values does not exceed the LOC for both non-listed and listed plant species beyond a distance of 50 feet from the edge of a site (**Table 4.15**), suggesting exposure is limited to the treated site. Nevertheless, with the least sensitive NOAEC (corn) of the 10 test species not exceeding the LOC for listed species inhabiting semi-aquatic areas beyond the edge of a treated site as well (**Table 4.16**), it is anticipated that potential risk to not all but some listed terrestrial plants exposed to off-site drift is likely.

Overall, there is a potential of risk for adverse effects on survival and growth to terrestrial monocots and dicots, including Federally-listed endangered and threatened species, that inhabit dry and semi-aquatic areas adjacent to tebuthiuron-treated fields through a combination of runoff and spray drift or by drift alone. Spray drift from granular/pelleted/tableted uses is expected to be negligible; however, risk to plants from runoff-borne residues alone cannot be discounted (**Discussed in Table 4.10**).

Table 4.13. Spray Drift (Terrestrial) Assessment for Non-target Listed and Non-listed Terrestrial Plant Species[a]

No. of Applications and Application Rate (lb a.i/.A)	Distance from Edge of Field	% of Application Rate	Dry Area EEC (lb a.i./A)	Non-listed Plant RQ	Listed Plant RQ	Spray Method
Terrestrial plants inhabiting dry areas						
1 @ 6	0 feet	0.5	3	**167**	**938**	Aerial
1 @ 6	50 feet	0.17	1	**56**	**313**	
1 @ 6	500 feet	0.02	0.1	**6**	**31**	
1 @ 6	997 feet	0.01	0.07	**4**	**22**	
1 @ 6	0 feet	1	6.0	**352**	**1978**	Ground
1 @ 6	50 feet	0.05	0.3	**17**	**94**	
1 @ 6	500 feet	0.004	0.02	**1**	**6**	
1 @ 6	997 feet	0.001	0.0085	0.7	**3**	

[a] Based on carrot EC_{25} of 0.018 lb a.i./A and EC_{05} of 0.0032 lb a.i./A.
*Value in bold indicates the LOC is exceeded.

Table 4.14. Spray Drift (Aquatic) Assessment for Listed and Non-Listed Terrestrial Plant Species [a]

No. of Applications and Application Rate (lb a.i./A)	Distance from Edge of Field	% of Application Rate	Semi-Aquatic EEC (lb a.i./A)	Non-listed Plant RQ	Listed Plant RQ	Spray Method
Terrestrial plants inhabiting semi-aquatic areas						
1 @ 6	0 feet	0.1	0.8	**44**	**250**	Aerial
1 @ 6	50 feet	0.07	0.4	**22**	**125**	
1 @ 6	500 feet	0.02	0.1	**6**	**31**	
1 @ 6	997 feet	0.01	0.07	**4**	**22**	
1 @ 6	0 feet	0.06	0.37	**21**	**116**	Ground
1 @ 6	50 feet	0.02	0.1	**6**	**31**	
1 @ 6	500 feet	0.003	0.02	**1**	**6**	
1 @ 6	997 feet	0.001	0.007	0.4	**2**	

[a] Based on carrot EC_{25} of 0.018 lb a.i./A and EC_{05} of 0.0032 lb a.i./A
*Value in bold indicates the LOC is exceeded.

Table 4.15. Spray Drift (Terrestrial) Assessment for Least Sensitive Terrestrial Plant Species [a]

No. of Applications and Application Rate (lb a.i/.A)	Distance from Edge of Field	% of Application Rate	Dry Area EEC (lb a.i./A)	Non-listed Plant RQ	Listed Plant RQ	Spray Method
Terrestrial plants inhabiting dry areas						
1 @ 6	0 feet	50	3	0.97	**1.5**	Aerial
1 @ 6	50 feet	17	1	<0.1	0.5	
1 @ 6	0 feet	100	6	**1.9**	**3**	Ground
1 @ 6	50 feet	1.7	0.1	0.03	0.05	
1 @ 4	0 feet	50	2	0.6	**1**	Aerial
1 @ 4	50 feet	17	0.7	0.2	0.4	
1 @ 4	0 feet	100	4	**1.3**	**2**	Ground
1 @ 4	50 feet	1.7	0.07	0.02	0.04	

[a] Based on corn EC_{25} of 3.1 lb a.i./A and NOAEC of 2.0 lb a.i./A.
*Value in bold indicates the LOC is exceeded.

Table 4.16. Spray Drift (Aquatic) Assessment for Least Sensitive Terrestrial Plant Species[a]

No. of Applications and Application Rate (lb a.i/.A)	Distance from Edge of Field	% of Application Rate	Semi-aquatic Area EEC (lb a.i./A)	Non-listed Plant RQ	Listed Plant RQ	Spray Method
Terrestrial plants inhabiting semi-aquatic areas						
1 @ 6	0 feet	13	0.75	0.2	0.4	Aerial
1 @ 6	50 feet	7.3	0.44	0.1	0.2	
1 @ 6	0 feet	6.2	0.37	0.1	0.2	Ground
1 @ 6	50 feet	1.9	0.11	0.04	0.06	
1 @ 4	0 feet	13	0.5	0.2	0.3	Aerial
1 @ 4	50 feet	7.3	0.29	0.09	0.1	
1 @ 4	0 feet	6.2	0.25	0.08	0.1	Ground
1 @ 4	50 feet	1.9	0.08	0.03	0.04	

[a] Based on corn EC_{25} of 3.1 lb a.i./A and NOAEC of 2.0 lb a.i./A.
*Value in bold indicates the LOC is exceeded.

Risk to Beneficial Insects and Terrestrial Invertebrates

The available beneficial insect toxicity data, based on tests with honeybees, suggest that the TGAI is practically non-toxic to bees on an acute contact basis. The LD_{50} value is >100 µg a.i./bee. Risk to beneficial insects in the direct treatment area exposed to tebuthiuron is expected to be minimal; consequently, precautionary labeling for honeybee protection is not required at this time.

For the assessment on terrestrial invertebrates, no mortality occurred in the honeybee study at concentrations as high as 100 µg a.i./bee. However, two studies (Doerr, T.B. 1980 and Zavaleta, J. 2012) suggest tebuthiuron does not affect terrestrial invertebrates, but increases the abundance and number of families in treated areas compared to untreated areas. However, Zavaleta reported that selected individual invertebrate taxonomic groups reacted differently to treatment with a 200% increase in grasshoppers and a 92% decrease in caterpillar larvae; treehoppers were not affected. No toxicity endpoints were provided; thus, it was not possible to assess whether the reduction in the larvae of caterpillars was a result of tebuthiuron treatment or a reduction in forb cover. Hagen et al. (2005) and Jamison (2002) suggest invertebrate abundance is dependent on herbaceous cover and structure, with invertebrates increasing in treated areas with more forb than in untreated areas.

Regardless of the effects, the adverse effects of the use patterns outside the target area would extend no farther than 100 feet off site. According to AgDRIFT and bee toxicity as a surrogate value, the potential for risk to non-target terrestrial invertebrates adjacent to treated sites exposed to tebuthiuron falls below the interim LOC of 0.05 for terrestrial invertebrates at approximately 100 feet off-site from the edge of the field as a result of aerial application. (**Table 4.17**). Until definitive endpoints are available for listed terrestrial invertebrates, it is uncertain whether all, some, or none of the listed terrestrial invertebrates would be adversely affected when exposed directly to tebuthiuron.

In addition, there is an uncertainty of the LOC exceedances for terrestrial invertebrates. While the RQ of 0.36 may exceed the LOC of 0.05, it is uncertain whether there are actually any adverse effects for terrestrial invertebrates since no effects occurred at the highest dose tested. The highest RQ could be much lower than 0.36.

Table 4.17. Spray Drift (Terrestrial) Assessment for Listed Terrestrial Invertebrate Species [a]					
No. of Applications and Application rate (lb a.i/.A)	**Distance from Edge of Field**	**% of Application Rate**	**Dry Area EEC (lb a.i./A)**	**Listed Terrestrial Invertebrate RQ**	**Spray Method**
Terrestrial invertebrates inhabiting dry areas					
1 @ 6	0 feet	0.5	3	**0.36**	Aerial
1 @ 6	50 feet	0.17	1	**0.12**	
1 @ 6	100 feet	0.1	0.6	**0.07**	
1 @ 6	500 feet	0.02	0.1	<0.01	

[a] Based on honeybee LD_{50} of >100 µg a.i./bee where 0% mortality was observed. This is equivalent to an exposure of 780 mg/kg body weight or 8.3 lb T-REX/A assuming 1.0 lb/A = 94 mg T-REX arthropod/kg for terrestrial invertebrates.
*Value in bold indicates the LOC of 0.05 is exceeded.

Taxa Exposed to Tebuthiuron As a Result of Spot Treatment Applications

There is uncertainty with the risk assessment for spot treatment uses. EFED has modified the risk assessment for spot treatment uses using an assumption that the rates are broadcast (**Table 4.18**). While aerial applications is permitted in some labels; however, to characterize the risks from spot treatment uses, only ground and granular application scenarios were used. EFED believes that exposure estimates for resources are overly conservative for spot treatments because the underlying assumption in the models is that 100% of the field is treated with the pesticide. In order to better characterize the importance of the 100% area treated assumption on the overall risk conclusions; an estimate of the area threshold of spot treatment for each taxon where the LOC would no longer be exceeded is given.

As an example, it is estimated that for the highest application rate (i.e. 6 lbs a.i./acre) the area treated would need to exceed 10% for the LOC to be exceeded for birds. However, EFED does not have information on typical spot treatment area percentages. Also, the labels that do specify spot treatment and the total area the container can cover (square feet) can be compared with **Table 4.18** to determine whether effects are possible from these uses.

Table 4.18 Area Percentage of Spot Treatment Uses (Spray or Granules) Needed to Exceed the LOC				
Taxa	**Application rates (lb a.i./A)**	**RQs assuming 100% area treated (highest to lowest)***	**LOC**	**Area Percentage of application needed to exceed LOC[1]**
Birds (acute effects, liquid spray, broadcast)	6	**0.98**	Acute = 0.1	10%
	4	**0.66**		15%
Mammals (acute effects, liquid spray, broadcast)	6	**1.6**		6%
	4	**1.1**		9%
Birds (acute effects, granules and pellets, broadcast)	6	No granule or pellets RQs were calculated; assumed equivalent to liquid spray RQs		--
	4			--
Mammals (acute effects, pellets, broadcast)	6	**1.96**		5%
	4	**1.31**		8%
Mammals (acute effects, granules, broadcast)	6	**0.24**		42%
	4	**0.16**		63%
Birds (chronic effects, broadcast, dietary-based)	6	**14**	Chronic = 1.0	7%
	4	**10**		10%
Mammals (chronic effects, liquid spray, broadcast, dietary-based)	6	**7**		14%
	4	**5**		20%
Mammals (chronic effects, broadcast, liquid spray, dose-based)	6	**45**		2%
	4	**30**		3%
Terrestrial Plants (non-listed effects, liquid spray, ground, broadcast)	6	**170**	Non-listed and listed plants = 1.0	0.6%
	4	**113**		0.9%
Terrestrial Plants	6	**956**		0.1%

Table 4.18 Area Percentage of Spot Treatment Uses (Spray or Granules) Needed to Exceed the LOC				
Taxa	**Application rates (lb a.i./A)**	**RQs assuming 100% area treated (highest to lowest)***	**LOC**	**Area Percentage of application needed to exceed LOC[1]**
(listed effects, liquid spray, ground, broadcast)	4	**638**		0.2%
Terrestrial Plants (non-listed effects, granules, ground, broadcast)	6	**167**		0.6%
	4	**111**		0.9%
Terrestrial Plants (listed effects, granules, ground, broadcast)	6	**938**		0.1%
	4	**625**		0.2%
Aquatic vascular plants (non-listed effects, liquid spray, ground, broadcast)	6	**8**		13%
	4	**5**		20%
Aquatic vascular plants (listed effects, liquid spray, ground, broadcast)	6	**20**		5%
	4	**14**		7%
Aquatic nonvascular plants (non-listed effects, liquid spray, ground, broadcast)	6	**20**		5%
	4	**14**		7%
Aquatic nonvascular plants (listed effects, liquid spray, ground, broadcast)	6	**26**		4%
	4	**18**		6%
Aquatic vascular plants (non-listed effects, granules, ground, broadcast)	6	**8**		13%
	4	**5**		20%
Aquatic vascular plants	6	**20**		5%
	4	**13**		8%

Table 4.18 Area Percentage of Spot Treatment Uses (Spray or Granules) Needed to Exceed the LOC				
Taxa	**Application rates (lb a.i./A)**	**RQs assuming 100% area treated (highest to lowest)***	**LOC**	**Area Percentage of application needed to exceed LOC[1]**
(listed effects, granules, ground, broadcast)				
Aquatic nonvascular plants (non-listed effects, granules, ground, broadcast)	6	**20**		5%
	4	**13**		8%
Aquatic nonvascular plants (listed effects, granules, ground, broadcast)	6	**26**		4%
	4	**17**		6%

*Bold values indicate LOC exceedance

[1] The threshold percentage is assessed to determine how much percent of exposure that RQ needs to exceed the LOC. For example, the highest acute RQ for birds inhabiting a field treated at 6 lb a.i./A is 0.98, which is up to 10x the listed species LOC of 0.1; to assess the % of exposure needed at which the LOC exceedance occurred, results indicate 10% is needed for the RQ to exceed the LOC. A "no effect" or "may affect" determination was not made since it is unknown what % of an actual area is typical spot treatment.

5. Federally Threatened and Endangered (Listed) Species Concerns

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, and/or the United States Fish and Wildlife Service (USFWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated critical habitat. Each federal agency is required under the Act to ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species" (50 C.F.R. § 402.02).

To facilitate compliance with the requirements of the Endangered Species Act (subsection (a)(2)), the Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly appreciably reduce the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (USEPA, 2004). After the Agency's screening level risk assessment is conducted, if any of the Agency's listed species' LOCs are exceeded for either direct or indirect effects, an analysis is conducted to determine if any listed or candidate species may co-occur in the area of the proposed pesticide use or areas downstream or downwind that could be contaminated from drift or runoff/erosion. If listed or candidate species may be present in the proposed action area, further biological assessment is undertaken. The extent to which listed species may be at risk is considered, which then determines the need for the development of a more comprehensive consultation package, as required by the Endangered Species Act.

The federal action addressed herein is the proposed renewed registration of tebuthiuron on agricultural use sites. It is expected that its use could occur nationwide.

5.1. Action Area

For listed species assessment purposes, the action area is considered to be the area affected directly or indirectly by tebuthiuron use and not merely the immediate area where tebuthiuron is applied. At the initial baseline, the risk assessment considers broadly described taxonomic groups and conservatively assumes that listed species within those broad groups are co-located with the pesticide treatment area. This means that listed terrestrial plants and wildlife are assumed to be located on or adjacent to the treated site and listed aquatic organisms are assumed to be located in a surface water body adjacent to the treated site. The assessment also assumes that the listed species are located within an assumed area, which has the relatively highest potential exposure to the pesticide, and that exposures are likely to decrease with distance from the treatment area.

5.2. Taxonomic Groups Potentially at Risk

If the assumptions associated with the baseline action area result in RQs that are below the listed species LOCs, a "no effect" determination conclusion is made with respect to listed species in that taxa, and no further refinement of the action area is necessary. Furthermore, RQs below the listed species LOCs for a given taxonomic group indicate no concern for indirect effects on listed species that depend upon the taxonomic group for which the RQ was calculated. However, in situations where the screening assumptions lead to RQs in excess of the listed species LOCs for a given taxonomic group, a potential for a "may affect" conclusion exists and may be associated with direct effects on listed species belonging to that taxonomic group or may extend to indirect effects upon listed species that depend upon that taxonomic group as a resource. In such cases, additional information on the biology of listed species, the locations of these species, and the locations of use sites are considered to determine the extent to which screening assumptions regarding an action area apply to a particular listed organism. These subsequent refinement steps will consider how this information would impact the action area for a particular listed organism and potentially include areas of exposure that are downwind and downstream of the pesticide use site.

Assessment endpoints, exposure pathways, and the conceptual models addressing tebuthiuron uses, and the associated exposure and effects analyses conducted for the tebuthiuron baseline risk assessment are in **Sections 2 to 3**. The assessment endpoints used in the baseline risk assessment include those defined operationally as reduced survival and reproductive impairment for both aquatic and terrestrial animal species and survival, reproduction, and growth of aquatic and terrestrial plant species from both direct acute and chronic exposures. These assessment endpoints are intended to address the standard set forth in the Endangered Species Act requiring federal agencies to ensure that any action they authorize does not appreciably reduce the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species. Risk estimates (RQs) which, integrating exposure and effects, are calculated for broad based taxonomic groups in the screening-level risk assessment presented in **Section 4.**

Both acute endangered species and chronic risk LOCs are considered in the baseline risk assessment to identify direct and indirect effects to taxa of listed species. This section identifies direct effect concerns, by taxa that are triggered by exceeding endangered LOCs in the baseline risk assessment, with an evaluation of the potential probability of individual effects for exposures that may occur at the established endangered species LOC. Data on exposure and effects collected under field and laboratory conditions are evaluated to make determinations on the predictive utility of the direct effect screening assessment findings to listed species. Potential for direct effects to listed taxa are described in **Table 5.1**.

Table 5.1. Potential Effects to Federally-Listed Taxa Associated with Direct Effects from the Registered Uses of Tebuthiuron.

Listed Plant Taxon	**Potential Direct Effects**	
Terrestrial and semi-aquatic plants – monocots and dicots	Yes*	
Aquatic nonvascular plants	Yes*	
Aquatic vascular plants	Yes*	
Listed Animal Taxon	**Potential Direct Effects**	
	Acute	**Chronic**
Terrestrial invertebrates	Uncertain[1]	N/A[2]
Mammals	Yes*	Yes*
Birds	Yes* for small-sized classes; No effect for mid- and large-sized classes	Yes* (all size classes)
Reptiles[3]	Yes*	Yes*
Terrestrial-phase amphibians[3]	Yes*	Yes*
Freshwater fish	No Effect	No Effect
Aquatic-phase amphibians[4]	No Effect	No Effect
Freshwater invertebrates	No Effect	No Effect
Estuarine/marine fish	No Effect	No Effect
Estuarine/marine invertebrates	No Effect	No Effect

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Appendix A

Environmental Fate Studies Summary

Hydrolysis (MRID 00020779)
^{14}C tebuthiuron (radiochemical purity~ 99.5%), at 10 and 100 ppm, did not degradf during 64 days of incubation in sterile aqueous solutions at pH 3, 6, and 9 in the dark at 25 °C.

Photodegradatoin in water (MRID 41328001)
Tebuthiuron did not photodegrade in sterile aqueous buffered (pH 5) solutions that were Continuously irradiated for 33 days With a xenon light source at approximately 25 °C. Tebuthiuron was the only compound identified in the irradiated and dark control solutions at all sampling intervals. At 33 days posttreatment, tebuthiuron comprised 96.3-97. % and 99.7-100% of the recovered radioactivity in the irradiated and dark control solutions, respectively. The major products of photodegradation were soil bound residues and five minor products (each less than 7% of applied radioactivity).

Photodegradatoin in soil (MRID 41050201)

Asieved (2mm) sandy loam soil (60% sand, 22 % silt , 12 % clay , 1.4% organic matter , 11.86% field moisture capacity at 0.33 bar , 5.7 pH, 4.9 meq/100g CEC and 1.28 g/ml bulk density) was used in this study . Thin layers of soil in petri dishes were fortified with 28.0 ppm of thiadiazol ring - labeled ^{14}C-tebuthiuron (specificactivity , 17.1 uCi/mg and 97.2% radio purity) and non radio labeled tebuthiuron at a rate o f 588.5 ppm. tebuthiuron photolyzed on soil with a half-life of 39.7 days.

Aerobic soil metabolism (MRID 41328001)
In a 9-month study, thiadiazole-labeled 14C tebuthiuron, at a concentration of 6 ppm in sandy loam soil incubated in darkness at 24 °C and 75% field moisture capacity, degraded with a half-life (calculated by the registrant) of 35.4 months. The degradates identified by two-dimensional TLC were N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea (degradate 104), N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-methylurea (compound 105), 5-(1,1-dimethylethyl)-2 methylamino-1,3,4-thiadiazol (compound 107), and 5-(1,1- dimethylethyl)-2 amino-1,3,4-thiadiazol (compound 108). The concentration of degradate 104, which accounted for 6.9% of the applied radioactivity after 9 months of incubation, appeared to be increasing at the end of the experiment.

Anaerobic soil metabolism (MRID41328002)

Following 30 days of aerobic incubation at 24 ± 1 °C and 75% of 0.33 bar moisture capacity and 60 days under flooded conditions in a sandy loam soil, thiadiazole-labeled 14C tebuthiuron (nominal concentration 6 ppm) exhibited very little metabolism. After 60 days of anaerobic incubation, the concentration of parent tebuthiuron had decreased 4.7% from the concentration at initiation of flooding. Degradates identified were N-[5-:(1,1-dimethylethyl)- 1,3,4-thiadiazol-2-yl]-N-methylurea (compound·104), N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-methylurea (compound 105), and N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-(hydroxymethyl)-N-methylurea (compound 109).

Anaerobic aquatic metabolism (MRID 41913101)

Tebuthiuron degrad~d with a half-life (calculated by the registrant) of> 1 year in anaerobic system containing pond water and sediment incubated for 365 days in darkness at 25.5 ± 0.8 °C. During the study there was very little degradation oftebuthiuron, with 93.7% the applied radiocarbon remaining as parent material at day 365. Degradates were repqrted to comprise approximately 1.4% of the applied radioactivity at the termination of the study.

Aerobic aquatic metabolism (MRID 41372501)
Tebuthiuron did not degrade appreciably in pond water and sediment that was incubated in darkness at 24 ± 1 °C fro 4 weeks under aerobic conditions. After 4 weeks of incubation, 95.2% of the applied radioactivity was present in parent tebuthiuron. Degradates identified by two-dimensional TLC were N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea (compound 1 04), N-[5-(1, 1-dimethylethyl)-1 ,3,4-thiadiazol-2-yl]-N' -methyl urea (compound 105), 5-(1,1-dimethylethyl)-2 methylamino-1,3,4-thiadiazol (compound 107), 5-(1,;1-Dimethylethyl)-2-amino-1,3,4-thiadiazol (compound 108), and N-[5-(1-1, dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-(hydroxymethyl)-N-methylurea (compound 109).

Leaching, Adsorption/Desorption (MRID 40768401)
Tebuthiuron is mobile in all 4 soils and has a Kads for sand, sandy loam, loam, boe!dmbz loam of 0.11, 0.62, 0.82, and 1.82, respectively. The corresponding Koc values are 38, 716! 75, and 152, respectively.

Bioaccumulation in fish (MRID 40819501)

In a 28-day flow-through study in which bluegill sunfish were exposed to a nominal tebuthiuron concentratio11 of 5.0 ppm, bioconcentration factors of 1.98, 3.40, and 2.63 were reported for edible tissue, nonedible tissue, and whole fish, respectively. Residues in the tissues consisted primarily of tebu thiuron and two metabolites N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-(hydroxymethyl)-N-methylurea (compound 109) and compound 103(OH) (hydroxylated form of parent tebuthiuron). Accumulated residues depurated rapidly from fish tissue with depuration half-lives of0.33 and 0.51 days reported for edible and lqnedible tissue, respectively. Based on the reported octanollwater coefficient (log Kow=1.79), there is slight potential for tebuthiuron residues to accumulate in fish.

Terrestrial Field Dissipation (MRID 43318101)

Tebuthiuron was broadcast applied once 'as a spray at nominal application rates of 6.6 lb ai/ A on bareground plots of Lakeland fine sand (Florida), Watsonville sandy loam (California), and Sharpsburg silty clay loam (Nebraska). EFED calculated soil dissipation half-lives for Florida Of 385 days(r2 = 0.66) for the total parent (summed across 0 to 72 inches) and 123 days (r2 = 0.92) for the surface layer (0 to 6 inches), for California of 770 days (r2 = 0.89) for the total parent (summed across 0 to 72 inches) and 462 days (r^2 = 0.97) for the surface layer (0 to 6 inches), and for Nebraska of 575 days (r2 = 0.89) for the total parent (summed across 0 to 72 inches) and 433 days (r2 = 0.91) for the surface layer (0 to 6 inches). The registrant calculated halflives (total parent profile) of383 days for Florida, 806 days for California, and 575 days for Nebraska.

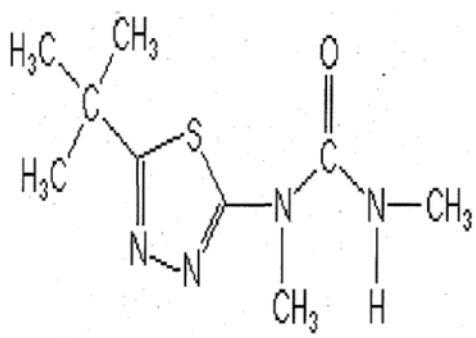
Tebuthiurori was detected in the deepest soil sample (60 to 72 inches) at the Florida site indicating that migration to ground water is a concern. · Tebuthiuron was not detected below 24 to 30 inches at the California site or below 30 to 36 inches at the Nebraska site, although these depths indicate that tebuthiuron is leaching. The metabolite (Compound 109383) was detected at all three sites but was not observed to have migrated below 6 to 12 inches in Florida, 12 to 18 inches in California, and 0 to 6 inches in Nebraska. The registrant did not calculate the half life for the metabolite. EFED estimated the half life for the metabolite from each study by performing linear regression on the decline pattern (as determined by peak concentration of metabolite). EFED calculated half lives for the total profile for Florida, California, and Nebraska, respectively were 81 days (r2 = 0.92), 495 days (r2 =0.96), and 385 days (r2 = 0.57).

Finally, it should be noted that evaporation exceeded water input at the Califonia and Nebraska sites and therefore the vertical movement (leaching potential) of tebuthiuron and its degradate may be underestimated at these two sites. The reported data indicate that tebuthiuron is mobile and persistent. Based on the data provided, leaching to ground water is likely to be a significant route of dissipation.

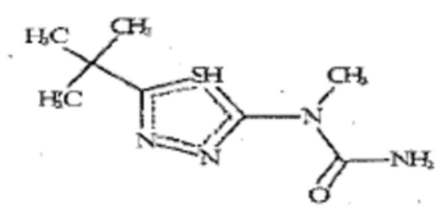
Small Scale Retrospective Ground Water Monitoring Study (MRID 42390901)
A small-scale retrospective ground water monitoring study was performed on a ran ch near Sarita, Texas, that has last been treated with tebuthiuron on March 24, 1986. The results of the study indicated that tebuthiuron was mobile enough to leach at least 15 feet to the water table, then still be present above minimum detection levels more than 4 years after the application. Soil sampling at and near the study site showed convincingly that tebuthiuron can persist at relatively high concentrations in soil and soil water if restrictive layer blocks leaching to the ground water.

Appendix B

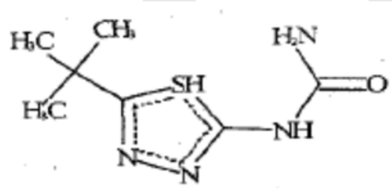
Chemical structures for the parent (tebuthiuron) and degradates 104, 106, 108, and 109



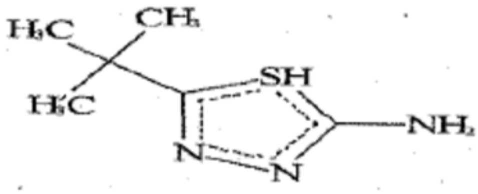
Tebuthiuron
N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-z-yl]-N,N-dimethylurea



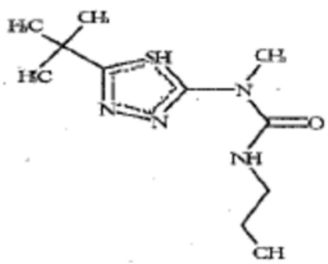
104: N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea



106: N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl] urea



108: 2-dimethylethyl-5-amino-1,3,4-thiadiazole



109: N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-hydroxymethyl-N-methylurea

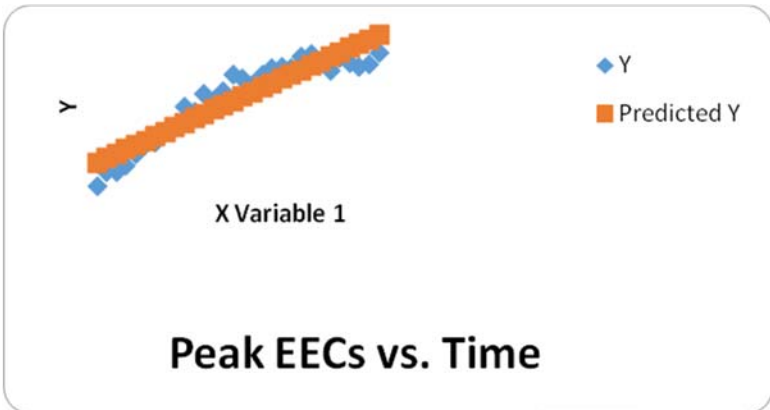
Appendix C

PRZM-EXAMS output files

Eco modeling
outputs.zip

Appendix D
Tebuthiuron pond accumulation with time

TXalfalfaOP (aerial)



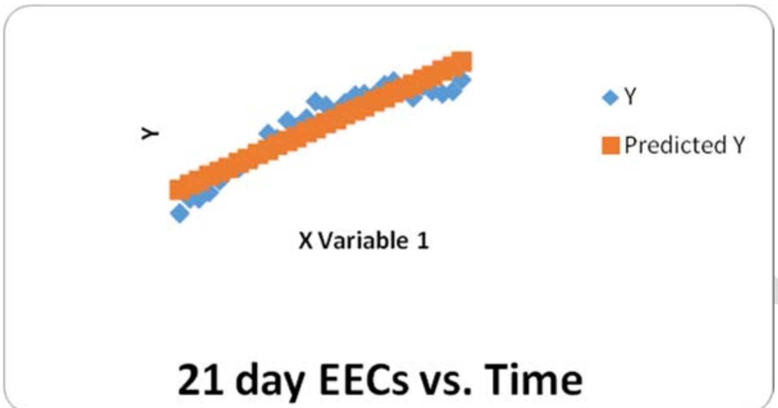
SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.933674633
R Square	0.871748319
Adjusted R Square	0.867167902
Standard Error	123.7752708
Observations	30

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	2915774	2915774	190.32073	5.189E-14
Residual	28	428968.89	15320.318		
Total	29	3344742.9			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	210.068046	46.350473	4.5321661	9.954E-05	115.12341	305.01269	115.12341	305.01269
X Variable 1	36.01862069	2.6108627	13.795678	5.189E-14	30.670511	41.36673	30.670511	41.36673



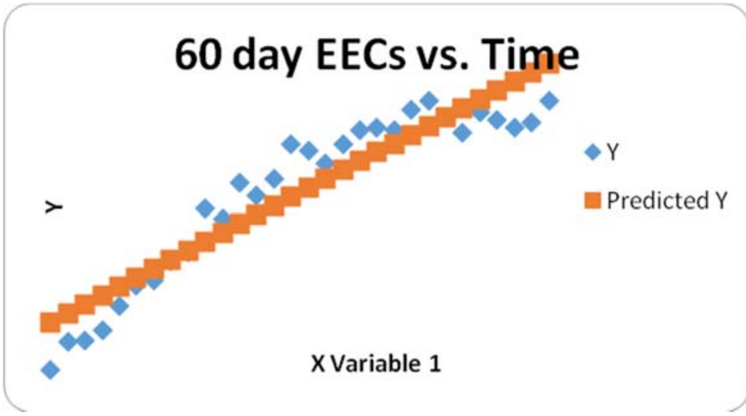
SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.9337579
R Square	0.8719039
Adjusted R Square	0.867329
Standard Error	123.20537
Observations	30

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	2893009.8	2893009.8	190.5858	5.101E-14
Residual	28	425027.79	15179.564		
Total	29	3318037.6			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	209.06	46.137062	4.5312811	9.98E-05	114.55251	303.56749	114.55251	303.56749
X Variable 1	35.877742	2.5988415	13.805283	5.1E-14	30.554256	41.201227	30.554256	41.201227



SUMMARY OUTPUT

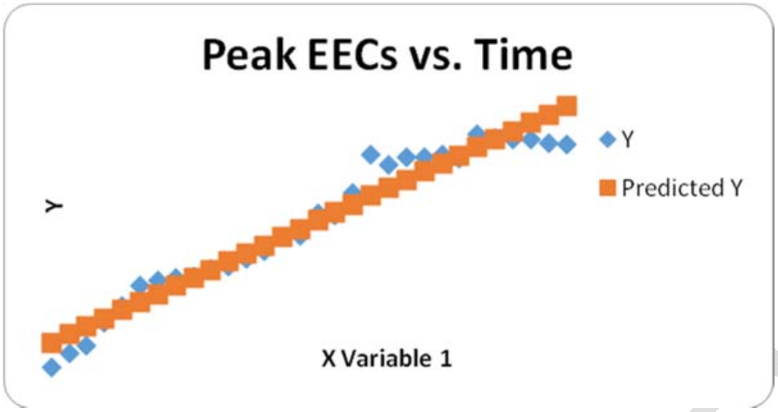
Regression Statistics	
Multiple R	0.9342
R Square	0.8727
Adjusted R Square	0.8681
Standard Error	122.3
Observations	30

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	2869847	2869847	191.8721	4.7E-14
Residual	28	418798.3	14957.08		
Total	29	3288645			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	205.85	45.79771	4.494775	0.00011	112.038	299.6627	112.038	299.6627
X Variable 1	35.734	2.579726	13.85179	4.7E-14	30.44949	41.01815	30.44949	41.01815

PAalfalfaOP (aerial)



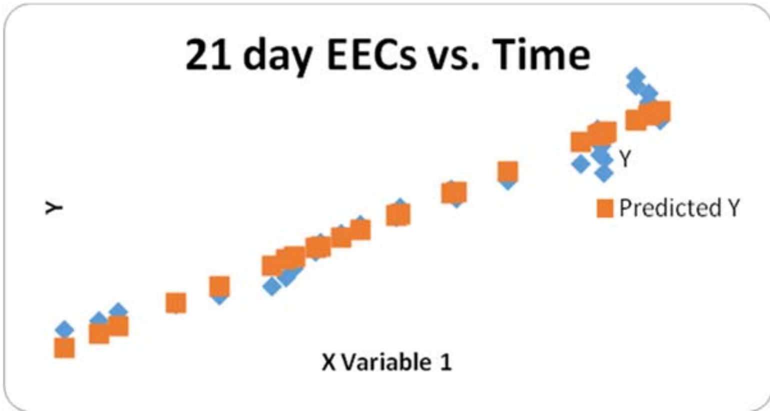
SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.9745036
R Square	0.9496573
Adjusted R Square	0.9478594
Standard Error	48.564216
Observations	30

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	1245722.9	1245722.9	528.1882	1.028E-19
Residual	28	66037.525	2358.483		
Total	29	1311760.5			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	80.422943	18.185978	4.42225	0.000134	43.170655	117.67523	43.170655	117.67523
X Variable 1	23.54295	1.0243928	22.982346	1.03E-19	21.444576	25.641323	21.444576	25.641323



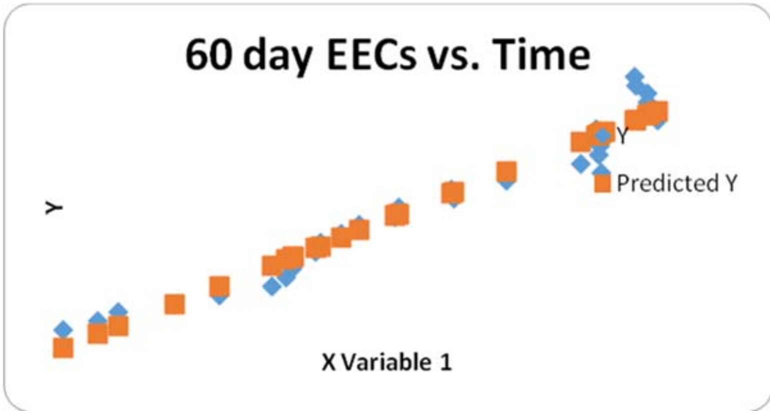
SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.9748338
R Square	0.9503009
Adjusted R Square	0.9485259
Standard Error	1.997309
Observations	30

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	2135.8012	2135.8012	535.3901	8.584E-20
Residual	28	111.69881	3.9892432		
Total	29	2247.5			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	1957.5453	0.8573801	2283.1707	2.49E-75	1955.789	1959.3015	1955.789	1959.3015
X Variable 1	0.0403955	0.0017458	23.138498	8.58E-20	0.0368194	0.0439716	0.0368194	0.0439716



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.9751028
R Square	0.9508254
Adjusted R Square	0.9490692
Standard Error	1.9867413
Observations	30

ANOVA

	df	SS	MS	F	Significance F
Regression	1	2136.9801	2136.9801	541.3995	7.397E-20
Residual	28	110.51994	3.9471408		
Total	29	2247.5			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	1957.5685	0.8517472	2298.2975	2.07E-75	1955.8238	1959.3132	1955.8238	1959.3132
X Variable 1	0.040447	0.001738	23.26799	7.4E-20	0.036886	0.044008	0.036886	0.044008

Appendix E
STIR Results for Tebuthiuron

Welcome to the EFED
Screening Tool for Inhalation Risk

This tool is designed to provide the risk assessor with a rapid method for determining the potential significance of the inhalation exposure route to birds and mammals in a risk assessment.

****NOTE**:** When entering values, press order to update linked cells.

Input	
Application and Chemical Information	
Enter Chemical Name	Teb
Enter Chemical Use	Rangeland
Is the Application a Spray? (enter y or n)	y
If Spray What Type (enter ground or air)	air
Enter Chemical Molecular Weight (g/mole)	228.3
Enter Chemical Vapor Pressure (mmHg)	3.00E-07
Enter Application Rate (lb a.i./acre)	6
Toxicity Properties	
Bird	
Enter Lowest Bird Oral LD_{50} (mg/kg bw)	2000
Enter Mineau Scaling Factor	1.15
Enter Tested Bird Weight (kg)	1.58
Mammal	
Enter Lowest Rat Oral LD_{50} (mg/kg bw)	388
Enter Lowest Rat Inhalation LC_{50} (mg/L)	3.696
Duration of Rat Inhalation Study (hrs)	4
Enter Rat Weight (kg)	0.35

Output		
Results Avian (0.020 kg)		
Maximum Vapor Concentration in Air at Saturation (mg/m^3)	3.69E-03	
Maximum 1-hour Vapor Inhalation Dose (mg/kg)	4.63E-04	
Adjusted Inhalation LD_{50}	7.66E+01	
Ratio of Vapor Dose to Adjusted Inhalation LD_{50}	6.05E-06	**Exposure not Likely Significant**
Maximum Post-treatment Spray Inhalation Dose (mg/kg)	5.76E-01	
Ratio of Droplet Inhalation Dose to Adjusted Inhalation LD_{50}	7.53E-03	**Exposure not Likely Significant**

Results Mammalian (0.015 kg)		
Maximum Vapor Concentration in Air at Saturation (mg/m^3)	3.69E-03	
Maximum 1-hour Vapor Inhalation Dose (mg/kg)	5.82E-04	
Adjusted Inhalation LD_{50}	2.20E+02	
Ratio of Vapor Dose to Adjusted Inhalation LD_{50}	2.65E-06	**Exposure not Likely Significant**
Maximum Post-treatment Spray Inhalation Dose (mg/kg)	7.25E-01	
Ratio of Droplet Inhalation Dose to Adjusted Inhalation LD_{50}	3.29E-03	**Exposure not Likely Significant**

Appendix F
SIP Results for Tebuthiuron

Table 1. Inputs

Parameter	Value
Chemical name	Teb
Solubility (in water at 25^{o}C; mg/L)	2500
Mammalian LD_{50} (mg/kg-bw)	388
Mammalian test species	laboratory rat
Body weight (g) of "other" mammalian species	
Mammalian NOAEL (mg/kg-bw)	20
Mammalian test species	laboratory rat
Body weight (g) of "other" mammalian species	
Avian LD_{50} (mg/kg-bw)	>2000
Avian test species	mallard duck
Body weight (g) of "other" avian species	
Mineau scaling factor	1.15
Mallard NOAEC (mg/kg-diet)	100
Bobwhite quail NOAEC (mg/kg-diet)	100
NOAEC (mg/kg-diet) for other bird species	
Body weight (g) of other avian species	
NOAEC (mg/kg-diet) for 2nd other bird species	
Body weight (g) of 2nd other avian species	

Table 2. Mammalian Results

Parameter	Acute	Chronic
Upper bound exposure (mg/kg-bw)	430.0000	430.0000
Adjusted toxicity value (mg/kg-bw)	298.4343	15.3832
Ratio of exposure to toxicity	1.4409	27.9526
Conclusion*	**Exposure through drinking water alone is a potential concern for mammals**	**Exposure through drinking water alone is a potential concern for mammals**

Table 3. Avian Results

Parameter	Acute	Chronic
Upper bound exposure (mg/kg-bw)	2025.0000	2025.0000
Adjusted toxicity value (mg/kg-bw)	#VALUE!	4.9613
Ratio of exposure to acute toxicity	#VALUE!	408.1627
Conclusion*	**#VALUE!**	**Exposure through drinking water alone is a potential concern for birds**

*Conclusion is for drinking water exposure alone. This does not combine all routes of exposure. Therefore, when aggregated with other routes (*i.e*., diet, inhalation, dermal), pesticide exposure through drinking water may contribute to a total exposure t

Appendix G
Tebuthiuron Ecological Effects Summaries

OCSPP 850.1010 – Daphnia Acute Toxicity Test

MRID 00041694
The acute toxicity of tebuthiuron to 10 hours old first instar daphnia was assessed for 48 hours. Nominal concentrations of the test material were set at 0 (control), 225, 300, and 400 mg a.i./L with 9, 10, 11 daphnia placed in each test vessel. All treatment and control groups were triplicated. There were 6, 50, and 97% mortality in the 225, 300, and 400 mg a.i./L treatment groups, respectively. Affected daphnia were reported light colored and lethargic swimming behavior followed by prostration, immobilization and death. The 48-hour EC_{50} (95% C.I.) was 297 (279-316) mg a.i./L, which would classify tebuthiuron to be practically nontoxic to trout, in accordance with the toxicity classification of USEPA.

The study is classified as scientifically sound and satisfies the guideline requirement for a freshwater invertebrate acute toxicity test with daphnia magna. The study is classified as acceptable.

OCSPP 850.1025 – Estuarine/marine Mollusk Shell Deposition

MRID 48722701
The 96-hour acute toxicity of tebuthiuron to the Eastern oyster, *Crassostrea virginica*, was studied under flow-through conditions. Oysters were exposed to the test material at nominal concentrations of 0 (negative control), 6.3, 13, 25, 50, and 100 mg a.i./L. Mean-measured concentrations were <LOD, 6.5, 14, 26, 50, and 95 mg a.i./L. Mortality and shell deposition were observed daily. No mortality was observed in the dilution water control or treatment groups. After 96 hours, the reviewer-calculated mean percent inhibition in shell growth compared to negative control was 26, 16, 7, 21, and 23% in the 6.5, 14, 26, 50, and 95 mg a.i./L test concentrations, respectively. The 96-hour EC_{50} based on shell deposition and mean measured concentrations was >95 mg a.i./L, categorizing tebuthiuron as practically non-toxic to the Eastern oyster.

The study is scientifically sound and satisfies the guideline requirements for an acute estuarine/marine invertebrate toxicity study with the Eastern oyster (*Crassostrea virginica*). This study is classified as acceptable.

OCSPP 850.1035 – Mysid Acute Toxicity Test

MRID 00041684

In a 96-hr acute toxicity study, Fiddler crab (*Uca pugilator*) a crustacean similar to the mysid shrimp were exposed to tebuthiuron at nominal concentrations of 0 (control), 10, 32, 100, 180, and 320 mg a.i./L. Mortality was 0, 0, 10, 0, 0, 20% in the 0 (control), 10, 32, 100, 180, and 320 mg a.i./L treatment groups, respectively, at test termination. The 96-hour LC_{50} was >320 mg a.i./L, which would classify tebuthiuron to be practically nontoxic to the Fiddler crabs, in accordance with the toxicity classification of USEPA.

This study is scientifically sound but does not satisfy the guideline requirement for a mysid shrimp acute toxicity study with Fiddler crab. This study is classified as supplemental since the fiddler crab is not a recommended test species.

OCSPP 850.1045 – Penaeid Acute Toxicity Test

MRID 00041684

In a 96-hr acute toxicity study, pink shrimp (P*enaeus duorarum*) were exposed to tebuthiuron at nominal concentrations of 0 (control), 10, 32, 100, 180, and 320 mg a.i./L. Mortality in the highest concentration was 100% at 24 hours, 100% in the 2nd highest concentration at 48 hours, and 11% and 77% in the 32 and 100 mg a.i./L treatment groups, respectively, at test termination. The 96-hour LC_{50} with 95% confidence intervals was 62 (39-90) mg a.i./L, which would classify tebuthiuron to be slightly toxic to pink shrimp, in accordance with the toxicity classification of USEPA.

This study is scientifically sound and satisfies the guideline requirement for a penaeid acute toxicity study with pink shrimp. This study is classified as acceptable.

OCSPP 850.1055 – Bivalve Acute Toxicity Test (embryo larval)

MRID 00041684

The acute toxicity of tebuthiuron to normal Eastern oyster (*Crassostrea virginica*) embryos was assessed for 48 hours. Nominal concentrations of tebuthiuron were 0 (seawater control), 32, 56, 100, 180, and 320 mg a.i./L. Three replicates per level. Each test replicate was inoculated with an estimated 27,000 ± 1350 embryos. The highest test concentration at 320 mg a.i./L nominal was the only level to experience mortality with 100% embryos dead. All other treatment groups embryos were normal at test termination. Since there were no concentration at which the percent reduction was between 100 and 0%, a definite LC_{50} could not be calculated. The 48-hour LC_{50} for eastern oyster embryos is estimated to be >180 and < 320 mg a.i./L. With an LC_{50} greater than 100 mg a.i./L, tebuthiuron is classified as practically nontoxic to Eastern oyster embryos, in accordance with the toxicity classification of USEPA.

This study is classified as scientifically sound and fulfills the guideline requirement for a bivalve (embryo larval) acute toxicity test with Eastern oyster. This study is classified as acceptable.

OCSPP 850.1075 – Freshwater and Estuarine/marine Fish Acute Toxicity

MRID 00020661 (Goldfish)

In a 96-hr acute toxicity study, goldfish (*Carassius auratus*) were exposed to tebuthiuron at nominal concentrations of 0 (control), 5, 10, 20, 40, 80, and 160 mg a.i./L without a solvent in the first test and at nominal concentrations of 0 (control), 6.25, 12.5, 25, 50, and 100 mg a.i./L with the solvent added in the second test. Goldfish were also exposed to the solvent alone at nominal concentrations of 0.33, 0.67, and 1.33 ml/L. Ten goldfish per replicate with two, three, four, or 6 replicates, depending on which test was performed. One fish died throughout the tests. The 96-hour LC_{50} was >160 mg a.i./L, which would classify tebuthiuron to be practically nontoxic to goldfish, in accordance with the toxicity classification of USEPA.

This study is scientifically sound however does not satisfy the guideline requirement for a freshwater fish acute toxicity study with *Carassius auratus*, due to several departures from guideline protocols. This study is classified as supplemental.

MRID 00020661 (Rainbow trout)
In a 96-hr acute toxicity study, rainbow trout (*Oncorhynchus mykiss*) were exposed to tebuthiuron at nominal concentrations of 0 (control), 1, 10, 50, 87, 120, and 160 mg a.i./L. Ten fish per test level. 10% mortality was observed in the highest level at 24 hours, which increased to 70% at 96 hours. Mortality was 20% in the 120 mg a.i./L test level at test termination. No fish died in the 87 mg a.i./L test level but dark coloration and lethargy in the fish were observed. The author reported the behavior of fish succumbing to the test material was generally similar to a syndrome characteristic of chemically poisoned fish. The gills of the trout at 160 mg a.i./L became irritated and inflamed exhibiting a red color although hemorrhaging was not prevalent. Moribund fish were then observed to become dark, lose equilibrium and then drop to the bottom of the test vessel where they eventually expired. The 96-hour LC_{50} (95% C.I.) was 143 (118-224) mg a.i./L, which would classify tebuthiuron to be practically nontoxic to trout, in accordance with the toxicity classification of USEPA.

This study is scientifically sound and satisfies the guideline requirement for a freshwater fish acute toxicity study with Rainbow trout, a warmwater fish. This study is classified as acceptable.

MRID 00020661 (Bluegill sunfish)
In a 96-hr acute toxicity study, bluegill sunfish (*Lepomis macrochirus*) were exposed to tebuthiuron at nominal concentrations of 0 (control), 1, 10, 50, 87, 120, and 160 mg a.i./L. Ten fish per test level. At 24 hours, mortality was 0, 0, 0, 0, 0, 10, and 10% in the 0 (control), 1, 10, 50, 87, 120, and 160 mg a.i./L test levels. At 96 hours, 90 and 100% were observed in the 120 and 160 mg a.i./L test group, respectively. Dark coloration and lethargy were observed in fish of the 87 mg a.i./L test level. The author reported the behavior of fish succumbing to the test material was generally similar to a syndrome characteristic of chemically poisoned fish. Moribund fish were then observed to become dark, lose equilibrium and then drop to the bottom of the test vessel where they eventually expired. The 96-hour LC_{50} (95% C.I.) was 106 (87-120) mg a.i./L, which would classify tebuthiuron to be practically nontoxic to bluegill sunfish, in accordance with the toxicity classification of USEPA.

This study is scientifically sound and satisfies the guideline requirement for a freshwater fish acute toxicity study with *Lepomis macrochirus*, a coldwater fish. This study is classified as acceptable.

MRID 00041685

In a 7-day acute toxicity study, fathead minnow (*pimephales promelas*) were exposed to a 98% technical formulation, an 80% wettable powder, and a 20% pelleted formulation of tebuthiuron at nominal concentrations equivalent to 0 (control), 70, 90, 110, 140, and 180 mg a.i./L. Ten fish per test level. Mortality was minimal in the tests however there were signs of sub-lethal effects. Sub-lethal effects observed were exploratory behavior and hypoactivity in concentrations at and greater than 140 mg a.i./L. Fish treated with 70, 90, 110 mg a.i./L of tebuthiuron appeared normal; however, periods of less aggressive feeding activity were observed compared to the control group throughout the test. The 96-hour LC_{50} was >180 mg a.i./L, which would classify tebuthiuron to be practically nontoxic to fathead minnow, in accordance with the toxicity classification of USEPA.

This study is scientifically sound but does not satisfy the guideline requirement for a freshwater fish acute toxicity study with *Pimephales promelas*, a warmwater fish. This study is classified as supplemental since study deviates from recommended protocol and inadequate reporting of the data.

MRID 48722702

In a 96-hr acute toxicity study, sheepshead minnows (*Cyprinodon variegates*), an estuarine/marine fish, were exposed to tebuthiuron at nominal concentrations of 0 (negative control), 6.3, 13, 25, 50, and 100 mg a.i./L under static-renewal conditions. Mean measured concentrations were <0.42 (<LOQ, negative control), 6.5, 13, 25, 50, and 98 mg a.i./L. There was no mortality observed in this study. The 96-hr LC_{50} was >98 mg a.i./L. Based on sub-lethal effects (loss of equilibrium) observed at 98 mg a.i./L, the NOAEC was determined to be 50 mg a.i./L, based on mean-measured concentrations. Based on the results of this study, tebuthiuron would be classified as **practically non-toxic** to *Cyprinodon variegatus* up to the exposure levels tested, in accordance with the classification system of the U.S. EPA.

This study is scientifically sound and satisfies the guideline requirement for an estuarine/marine fish acute toxicity study with *Cyprinodon variegatus*. This study is classified as acceptable.

OCSPP 850.1300 – Freshwater Invertebrate Life Cycle

MRID 00138700

In a 21-day static renewal full life cycle study, <24-hours first instar water fleas (*daphnia magna*) were exposed to tebuthiuron at nominal concentration of 0 (control), 5.63, 11.25, 22.5, 45, and 90 mg a.i./L. The mean-measured concentrations were 0 (control), 5.47, 11, 21.8, 44.2, and 90.2 mg a.i/L. Ten replicates per treatment level. Seven replicates with one daphnia each were used for fecundity and three replicates of five daphnia each were used for survival data. Two sets of replicates were used for control. No significant levels of mortality occurred at any of the levels tested. Daphnia from the 44.2 and 90.2 mg a.i./L treatment groups were significantly shorter than control daphnia. Daphnia from the 44.2 and 90.2 mg a.i./L treatment groups had significant reductions in number of broods per reproducing adult and number of offspring per adult when compared to control daphnia. Daphnia from the 90.2 mg a.i./L treatment group required a significantly longer time to release their first brood. As of a result of significant differences in growth and fecundity at the 44.2 and 90.2 mg a.i./L treatment levels, the NOAEC is 21.8 mg a.i/L. The LOAEC is 44.2 mg a.i./L.

This study is scientifically sound and satisfies the guideline requirement for a freshwater invertebrate life cycle study with *Daphnia magna.* This study is classified as acceptable.

OCSPP 850.1500 – Fish Full Life Cycle Toxicity Test

MRID 00090083

In a 45-day flow-through fish embryo-larval study, a total of 50 eyed embryos of Rainbow trout, *Oncorhynchus mykiss*, in each of two replicates per treatment were exposed to tebuthiuron at nominal concentrations of 0 (control), 3.1, 6.2, 12.5, 25, and 50 mg a.i./L. Mean-measured concentrations were 0 (control), 3.1, 6.3, 12.5, 25, and 52 mg a.i./L. On Day 2 when the hatching of all embryos was complete, a total of 25 normal larvae were transferred from the two egg cups in each replicate aquarium. These larvae were continuously exposed to the same treatment level for 43 days.

Hatching was 100% successful in all replicate aquaria. Survival was 100, 100, 98, 94, 92, and 80% in the control, 3.1, 6.3, 12.5, 26, and 52 mg a.i./L groups. Only exposure to the highest test concentration resulted in a statistically and biologically significant reduction of larvae survival at days 30 and 45. The behavior and feeding response of larvae in the treatment groups were considered normal when compared to control larvae. When compared to control larvae, the total length of the larvae in the highest test concentration was significantly reduced by test days 30 and 45. This reduction in mean length correlated well with an average weight of control larvae.

Statistically significant differences in total length of <6% were found on Day 30 between control larvae exposed in the 6.3, 12.5, and 25 mg a.i./L treatment groups. No weights were recorded on day 30 to substantiate this size difference and by day 45 statistically significant length differences at these concentrations did not exist. The differences noted on day 30 were therefore considered to be biologically insignificant.

Based on significant reduction in the survival and size of rainbow trout larvae at 52 mg a.i./L, the highest test concentration; the NOAEC is 26 mg a.i./L. This fish embryo-larval study was request in exchange of a fish full life cycle test. This study is scientifically sound and shows that a chronic exposure to tebuthiuron as low as 52 mg a.i./L can result in impaired reproduction and reduced growth in rainbow trout. This study is classified as acceptable.

MRID 00090084

In a 33-day flow-through fish embryo-larval study, a total of 50 embryos of fathead minnow, *Pimephales promelas*, in each of two replicates per treatment were exposed to tebuthiruon at nominal concentrations of 0 (control), 5, 10, 20, 40, and 80 mg a.i./L. Mean-measured concentrations were 0 (control), 4.7, 9.3, 18, 38, and 76 mg a.i./L. Four replicates were used for the water control. After hatch at day 5, larvae were transferred to the aquaria and were continuously exposed to tebuthiuron for 28 days.

Hatching was 93, 90, 88, 86, 90, and 95% in the control, 4.7, 9.3, 18, 38, and 76 mg a.i./L groups. Survival was 88, 90, 88, 85, 92, and 89% in these same groups. No significant reduction in hatching or survival of minnows was observed as high as 76 mg a.i./L. When compared to control larvae and the three highest concentrations, the larvae in the 18, 38 and 76 mg a.i./L groups were statistically significantly shorter. The NOAEC was 9.3 mg a.i./L.

This fish embryo-larval study with the fathead minnow was request in exchange of a fish full life cycle test. This study is scientifically sound and shows that a chronic exposure to tebuthiuron as low as 18 mg a.i./L can result in reduced growth but not reproductive effects in fathead minnows.

OCSPP 850.2100 – Avian Acute Oral

MRID 00041692

The acute oral toxicity of Tebuthiuron to 9-month-old mallard ducks (*Anas platyrhynchos*) was assessed over 14 days. Tebuthiuron was administered to the birds by gavage at nominal concentrations of 0 (control), 1000, and 2000 mg a.i./kg bw. No mortality was observed throughout the test in the treatment groups or control group. The 14-day acute oral LD_{50} was >2000 mg a.i/kg bw. According to the US EPA toxicity classification, tebuthiuron would be classified as practically nontoxic to mallard ducks on an acute oral basis.

Body weight was taken on days 3, 7 and 14; however, results were not reported. Food consumption was not observed or measured, the results are unknown. Signs of toxicity of anorectic, low appetite in females, hypoactivity, and lethargy were reported; however, by day two, birds were no longer hypoactivity or lethargy.

This toxicity study is classified as scientifically sound and satisfies the OCSPP 850.2100 guideline requirement for acute oral toxicity study for the mallard duck. This study is classified as acceptable.

MRID 00020661 (Bobwhite quail)

The acute oral toxicity of tebuthiuron to Northern bobwhite quail (*Colinus virginianus*) was assessed for 14 days. Tebuthiuron was administered to the birds by gavage at the limit dose of 500 mg a.i./kg bw nominal. No evidence of toxicity was observed during the test period and all birds survived. The behavior, appearance and appetite of the birds remained normal during the test period and each of the birds gained weight. The 14-day acute oral LD_{50} was >500 mg a.i/kg bw. No mortality occurred up to and at 500 mg a.i./kg bw, the limit dose; however, because the test concentration was not tested as high as 2,000 mg a.i./kg bw, a firm toxicity classification could not be made this time. As of a result, the study is classified as supplemental as the test did not comply with protocols recommended by the guideline for the following reasons: 1. The age of the birds was not reported, 2. Individual body weight and mean food consumption were not reported, and the test did not established a definite LD_{50}, neither does it show that the LD_{50} is greater than 2000 mg a.i./kg bw.

<u>MRID 00020661 (Mallard duck)</u>

The acute oral toxicity of tebuthiuron to one-year old mallard duck (*Anas platyrhynchos*) was assessed for 14 days. Tebuthiuron was administered to the birds by gavage at the limit dose of 500 mg a.i./kg bw nominal. No evidence of toxicity was observed during the test period and all birds survived. The behavior, appearance, and appetite of the birds remained normal during the test period and each of the birds gained weight. The 14-day acute oral LD_{50} was >500 mg a.i/kg bw. No mortality occurred up to and at 500 mg a.i./kg bw, the limit dose; however, because the test concentration was not tested as high as 2,000 mg a.i./kg bw, a firm toxicity classification could not be made this time. As of a result, the study is classified as supplemental as the test did not comply with protocols recommended by the guideline for the following reasons: Individual body weight and mean food consumption were not reported; the test did not established a definite LD_{50}, neither does it show that the LD_{50} is greater than 2000 mg a.i./kg bw.

<u>MRID 00020661 (Domestic chicken)</u>

The acute oral toxicity of tebuthiuron to adult chickens (*White Rock Cross*) was assessed for 14 days. Tebuthiuron was administered to the birds by gavage at the limit dose of 200 mg a.i./kg and in a second study at 500 mg a.i./kg bw nominal. In the 200 mg a.i./kg bw limit dose study, a slight hypoactivity and mild anorexia were noted 24 hours post-treatment; however, appeared normal thereafter. All birds survived and gained weight during the test period. In the 500 mg a.i./kg bw limit dose study, all chickens appeared normal, survived, and gained weight during the test period. The 14-day acute oral LD_{50} was >500 mg a.i/kg bw. No mortality occurred up to and at 500 mg a.i./kg bw, the limit dose; however, because the test concentration was not tested as high as 2,000 mg a.i./kg bw, a firm toxicity classification could not be made this time. As of a result, the study is classified as supplemental as the test did not comply with protocols recommended by the guideline for the following reasons: Individual body weight and mean food consumption were not reported; the test did not established a definite LD_{50}, neither does it show that the LD_{50} is greater than 2000 mg a.i./kg bw.

OCSPP 850.2200 – Avian Acute Dietary

<u>MRID 00041680</u>

The acute dietary toxicity of Tebuthiuron to 7 days old mallard ducks (*Anas platyrhynchos*) was assessed for 8 days. Tebuthiuron was administered to the ducks in the diet at nominal concentrations of 0 (control), 400, 1000, and 2500 mg a.i./kg diet. The 8-day acute dietary LC_{50} was >2500 mg a.i./kg diet, the highest concentration tested. No mortality occurred up to and at 2500 mg a.i./kg diet; however, because the test concentration was not tested as high as 5,000 mg a.i./kg diet, a firm toxicity classification could not be made this time.

Ten birds per test levels. The author reported there were no difference in behavior, appearance, and posture in the treated ducks when compared to the control group ducks. None of the groups appeared reluctant to eat the compound containing diets. With additional data submitted (MRID 41693) on food consumption and body weight gain, a significant reduction in food consumption in all treatment groups compared to the control was noted from day 0 to 5. With no significant reduction in body weight gain between treated and control groups and the small difference in food consumption, the apparent reduction in food consumption has probably not affected the outcome of the test significantly.

This toxicity study is classified as scientifically sound but does not satisfy the OCSPP 850.2200 guideline requirement for acute dietary toxicity study with the mallard duck. This study is classified as supplemental. Test concentrations were not tested as high as 5,000 mg a.i/kg diet.

MRID 00041681

The acute dietary toxicity of Tebuthiuron to 7 days old bobwhite quails (*Anas platyrhynchos*) was assessed for 8 days. Tebuthiuron was administered to the chicks in the diet at nominal concentrations of 0 (control), 400, 1000, and 2500 mg a.i./kg diet. The 8-day acute dietary LC_{50} was >2500 mg a.i./kg diet, the highest concentration tested. No mortality occurred up to and at 2500 mg a.i./kg diet; however, because the test concentration was not tested as high as 5,000 mg a.i./kg diet, a firm toxicity classification could not be made this time.

Ten chicks per test level were used. The author reported there were no difference in behavior, appearance, and posture in the treated quails when compared to the control group quails. None of the groups appeared reluctant to eat the compound containing diets. With additional data submitted (MRID 41693) on food consumption and body weight gain, a significant reduction in food consumption in all treatment groups compared to the control was noted from day 0 to 5. With no significant reduction in body weight gain between treated and control groups and the small difference was not pronounced in food consumption, the apparent reduction in food consumption has probably show that the test material is not toxic or has repellent effects.

This toxicity study is classified as scientifically sound but does not satisfy the OCSPP 850.2200 guideline requirement for acute dietary toxicity study with the bobwhite quail. This study is classified as supplemental. Test concentrations were not tested as high as 5,000 mg a.i/kg diet.

MRID 40601001

The acute dietary toxicity of Tebuthiuron to 11-day-old Northern bobwhite quail (*Colinus virginianus*) was assessed over 8 days. Tebuthiuron was administered to the birds in the diet at nominal concentrations of 0 (control), 600, 1200, 2500, and 5000 mg a.i./kg diet. Mean-measured concentrations were 0 (<LOQ, control), 636, 1210, 2573, and 5113 mg a.i./kg diet, respectively. No significant mortality or behavioral signs of toxicity were noted throughout the test. The 8-day acute dietary LC_{50} was determined to be >5113 mg a.i./kg diet. According to the US EPA classification, Tebuthiuron would be classified as **practically non-toxic** to bobwhite quails on an acute dietary basis.

One bird in the 1210 mg a.i./kg diet test group and one bird in the 5113 mg a.i./kg diet test group died during the three-day period that the birds were fed untreated diet. Both birds were the smallest in their pens and one was the smallest in the study. Both birds gained weight while feeding on the treated diet and no signs of toxicity were noted. It is possible that the stress of handling these small birds, for weighing on day 5 contributed to their deaths. No other mortalities or signs of toxicity were recorded during the study. Birds in the 2573 and 5113 mg a.i./kg diet test groups gained significantly less weight as compared with the control group during the 5-day treatment phase. However, there were no significant differences between mean body weight gain values of control and treatment birds during the 3-day basal diet phase. There were no significant differences between the mean food consumption of control birds and any of the treatment group birds during any phase of the study.

This toxicity study is classified as scientifically sound and satisfies the OCSPP 850.2200 guideline requirement for acute dietary toxicity study with the bobwhite quail. This study is classified as acceptable.

MRID 40601002

The acute dietary toxicity of Tebuthiuron to 4-day-old mallard ducks (*Anas platyrhynchos*) was assessed over 8 days. Tebuthiuron was administered to the ducks in the diet at nominal concentrations of 0 (control), 600, 1200, 2500, and 5000 mg a.i./kg diet. Mean-measured concentrations were 0 (<LOQ, control), 583, 1176, 2578, and 5093 mg a.i./kg diet, respectively. No mortality or behavioral signs of toxicity were noted throughout the test. The 8-day acute dietary LC_{50} was determined to be >5093 mg a.i./kg diet. According to the US EPA classification, Tebuthiuron would be classified as **practically non-toxic** to mallard ducks on an acute dietary basis.

During the five-day treatment phase, there was no significant difference between the mean body weight gain values of control birds and birds at the 583 mg a.i./kg diet level. However, ducks exposed to diets containing tebuthiuron concentrations of >1176 mg a.i./kg diet gained significantly less weight as compared with the control group. During the 3-day basal diet phase, there were no significant differences in mean body weight gain values of control and treat ducks. Ducks in the 2578 and 5093 mg a.i./kg diet mean-measured treatment levels ate significantly less food than control ducks. Ducks at the 1176 mg a.i./kg diet treatment level also consumed less food than control ducks, although this difference was not significantly significant. During the 3-day basal diet phase, ducks at the 2578 and 5093 mg a.i./kg diet test levels consumed less food than control ducks; however, these differences were not statistically significant.

This toxicity study is classified as scientifically sound and satisfies the OCSPP 850.2200 guideline requirement for acute dietary toxicity study with the mallard duck. This study is classified as acceptable.

MRID 48928201

The acute dietary toxicity of Tebuthiuron to 5-7 month-old Zebra Finches (*Taeniopygia guttata*) was assessed over 8 days. Tebuthiuron was administered to the birds in the diet at nominal concentrations of 0 (control), 562, 1000, 1780, 3160, and 5620 mg a.i./kg diet. Mean-measured concentrations were <50 (<LOQ, control), 497, 895, 1590, 2870, and 5380 mg a.i./kg diet, respectively. The 8-day acute dietary LC_{50} (with 95% C.I.) was 1465 (1145 to 1883) mg a.i./kg diet. According to the US EPA classification, Tebuthiuron would be classified as **slightly toxic** to Zebra Finches on an acute dietary basis.

Mortality was 80, 90, and 100% in the mean-measured 1590, 2870, and 5380 mg a.i./kg diet levels, respectively. During the exposure period, some birds were taken off of treated feed before the full 5-day exposure period was complete due to extremely reduced food consumption values. These birds were counted as mortalities.

Treatment-related decreases in body weight gains were observed at 895, 1590, and 2870 mg a.i./kg diet during the exposure period (Days 0-5). Body weight gains at these doses were comparable or greater than controls during the post-dosing period (Days 6-8). However, overall mean body weights were still reduced compared to controls in the 1590 and 2870 mg a.i./kg diet survivors. A direct comparison of body weights and body weight gains could not be made in the 5380 mg a.i./kg diet group as all birds were taken off of treated feed after only 2 days of exposure.

There was a slight reduction in food consumption noted in the 497 mg a.i./kg diet group. Treatment-related reductions in food consumption were observed at ≥895 mg a.i./kg diet during the exposure period (Days 0-5). Post-exposure food consumption was comparable to controls at all doses. Mean daily dietary doses were 115.6, 170.5, 211.3, 250.2, and 175.8 mg a.i./kg bw/day in the mean-measured 497, 895, 1590, 2870, and 5380 mg a.i./kg diet levels, respectively. Clinical signs of toxicity were observed as follows: at 497 mg a.i./kg, up to 50% of birds displayed slightly ruffled appearance and wing droop between Days 2 and 6; at 895 mg a.i./kg, up to 60% of birds displayed ruffled appearance and wing droop between Days 2 and 7; at 1590 mg a.i./kg, all birds displayed at least one clinical sign of toxicity (ruffled appearance, lethargy, and wing droop) by Day 4; at 2870 mg a.i./kg, all birds were noted with at least one clinical sign of toxicity (ruffled appearance, lethargy, wing droop, loss of coordination, prostrate posture, and loss of righting reflex) or died by Day 3; and at 5380 mg a.i./kg, all birds were noted with ruffled appearance by the afternoon of Day 1.

This toxicity study is classified as scientifically sound and satisfies the OCSPP 850.2200 guideline requirement for acute dietary toxicity study with the Zebra Finch. This study is classified as acceptable.

OCSPP 850.2300 – Avian Reproduction

MRID 00093690

The one-generation reproductive toxicity of tebuthiuron to 5-month-old mallard ducks (*Anas platyrhynchos*) was assessed over 22 weeks. Tebuthiuron was administered to the ducks in the diet at nominal concentrations of 0 (control), 20 and 100 mg a.i./kg diet. Measured concentrations in the diet were not significantly different.

There was no treatment-related mortality, signs of toxicity, or effects on body weight or food consumption at any dietary level. No significant reduction in the reproductive parameters of egg laid, eggs cracked, viable embryos, live three-week embryos, normal hatchlings, 14 day-old survivors, and eggshell thickness were observed. A statistically significant but non-dose –related reduction in 14-day old survivors was observed at the 20 mg a.i./kg-diet. With no tebuthiuron-related effects observed in mallard ducks up to and at 100 mg a.i./kg diet, the NOAEC is 100 mg a.i./kg-diet, the highest concentration tested.

This study is scientifically sound and fulfills the guideline requirement for a mallard duck (*Anas platyrhynchos*) reproductive toxicity study. This study is classified as acceptable.

MRID 00104243

The one-generation reproductive toxicity of tebuthiuron to 6-month-old bobwhite quails (*Colinus virginianus*) was assessed over 22 weeks. Tebuthiuron was administered to the chicks in the diet at nominal concentrations of 0 (control), 20 and 100 mg a.i./kg diet. Measured concentrations in the diet were not significantly different.

There was no treatment-related mortality, signs of toxicity, or effects on body weight or food consumption at any dietary level. No significant reduction in the reproductive parameters of egg laid, eggs cracked, viable embryos, live three-week embryos, normal hatchlings, 14 day-old survivors, and eggshell thickness were observed in the treatment groups compared to control group. With no tebuthiuron-related effects observed in bobwhite quails up to and at 100 mg a.i./kg diet, the NOAEC is 100 mg a.i./kg-diet, the highest concentration tested.

This study is scientifically sound and fulfills the guideline requirement for a bobwhite quail (*Anas platyrhynchos*) reproductive toxicity study. This study is classified as acceptable.

MRID 48928202

The one-generation reproductive toxicity of Tebuthiuron to 16 pairs per level of 22-week old mallards (*Anas platyrhynchos*) was assessed over 20 weeks. Tebuthiuron was administered to the birds in the diet at nominal concentrations of 0 (negative control), 500, 900, and 1500 mg a.i./kg diet. Mean-measured concentrations were <50 (<LOQ, control), 500, 903, and 1550 mg a.i./kg diet.

There were no treatment-related mortalities, signs of toxicity, or effects on body weight or food consumption at any dietary level. A statistically significant ($p<0.05$) dose-dependent reduction in hatchling body weight and eggshell thickness was observed at 1550 mg a.i./kg diet compared to the controls. There were statistically significant ($p<0.05$; Williams test, 26-41%) reductions from control in egg production (eggs laid per pen) in the 500, 903 and 1550 mg a.i./kg diet groups. A slight (<1%) reduction from control in eggs not cracked per eggs laid was detected at the lowest treatment level ($p = 0.04$), but was not considered to be treatment-related. No statistically significant differences in the other endpoints were observed between the control group and any of the treatment groups. Based on the dose-dependent reductions in eggs laid, the NOAEC could not be determined in this study (i.e., <500 mg a.i./kg diet).

This study is scientifically sound but does not satisfy the guideline requirement for a mallard (*Anas platyrhynchos*) reproductive toxicity study. The study is classified as supplemental due to significant effects in eggs laid at all test levels that a NOAEC could not be determined; while this deviation impacted the acceptability of the study, the reviewer felt this study provides useful information that it should not be rejected. This study was conducted with progressively higher concentrations of what was used in the original study (MRID 00093690) at which no effects in birds were observed at and up to 100 mg a.i./kg diet. Combining the studies with test levels at 20, 100, 500, 903, and 1550 mg a.i./kg diet, the resulting LOAEL and NOAEL would be 500 and 100 mg a.i./kg diet, respectively.

MRID 48928203

The one-generation reproductive toxicity of Tebuthiuron to 16 pairs per level of 36-week old Northern bobwhite quail (*Colinus virginianus*) was assessed over 20 weeks. Tebuthiuron was administered to the birds in the diet at nominal concentrations of 0 (negative control), 500, 900, and 1500 mg a.i./kg diet. Mean-measured concentrations were <50 (<LOQ, control), 500, 903, and 1550 mg a.i./kg diet.

No treatment-related mortalities were observed at any treatment level. Three control birds were found dead during Weeks 6, 13, and 14. One male bird in the 1550 mg a.i./kg group was euthanized on Day 4 of Week 16 due to fractured right leg. Adult male body weight gain was significantly reduced in a dose-dependent manner 53-121% at all treated levels, relative to the negative control ($p<0.05$, William's test). Adult female body weight was significantly reduced at the 1550 mg a.i./kg diet level, relative to the control ($p<0.01$; Jonckheere-Terpstra test). No statistically-significant differences were observed between the control group and any of the treated groups for food consumption. Offspring body weights were significantly reduced in a dose-dependent manner, with reductions from control detected at the 903 and 1550 mg a.i./kg diet levels for hatchling body weights ($p<0.01$; Jonckheere-Terpstra test) and at the 1550 mg a.i./kg diet level for 14-day old survivor weight ($p<0.05$; William's test).

No treatment-related effects on reproductive performance parameters were observed in the 500 mg a.i./kg diet group, but dose-dependent effects were detected for offspring survival. At 903 and 1550 mg a.i./kg diet, the offspring survival (14-day hatchlings per number hatched) was slightly (4-7%), but significantly reduced, compared to the control ($p<0.05$; Jonckheere-Terpstra test). Also, at the 1550 mg a.i./kg diet level, egg production was reduced 23%, from an average of 44.8 eggs laid per pen in the control group to 34.7 eggs laid per pen in the treated group ($p<0.05$; Jonckheere-Terpstra test); both the study author and reviewer concluded that this effect was treatment-related, despite the non-monotonicity of the data. No statistically significant differences in egg shell thickness were observed between the control group and any of the treatment groups. The reviewer concluded that the NOAEC could not be determined in this study due to dose-dependent reductions in adult male body weight gain (i.e., NOAEC<500 mg a.i./kg diet).

This study is scientifically sound but does not satisfy the guideline requirement for a Northern bobwhite quail (*Colinus virginianus*) reproductive toxicity study. The study is classified as supplemental due to significant effects in male weight gain at all test levels that a NOAEC could not be determined; while this deviation impacted the acceptability of the study, the reviewer felt this study provides useful information that it should not be rejected. This study was conducted with progressively higher concentrations of what was used in the original study (MRID 00104243) at which no effects in birds were observed at and up to 100 mg a.i./kg diet. If the studies were combined with test concentrations at 20, 100, 500, 903, and 1550 mg a.i./kg diet, the resulting LOAEL and NOAEL would be 500 and 100 mg a.i./kg diet, respectively.

OCSPP 850.3020 – Honeybee Acute Contact Toxicity Test

MRID 40840401

The acute contact toxicity of technical tebuthiuron to honey bees (*Apis mellifera*) was tested in the laboratory. In the 48-hour acute contact test, bees were exposed to technical tebuthiuron administered topically to the thorax, at an application rate of 0 (negative control), 0 (solvent control), 13, 22, 36, 60, and 100 µg a.i./bee. No treatment-related effects were noted throughout the study period. Mortality rates did not exceed 11% in any of the treatment groups; mortality in the negative and solvent controls was 5% and 7%, respectively. The 48-hour acute contact LD_{50} was >100 µg a.i./bee, the highest dose tested. According to the US EPA classification, Tebuthiuron would be classified as **practically non-toxic** to honeybees on an acute contact basis.

The study is scientifically sound and satisfies the guideline requirements for a honeybee acute contact toxicity test. This study is classified as Acceptable.

OCSPP 850.4100 – Seedling Emergence and Seedling Growth Toxicity Test

MRID 41066901

The effect of the technical grade of tebuthiuron on the seedling emergence of monocot (corn, *Zea mays*; wheat, *Triticum aestivum*; sorghum, *Sorghum bicolor*; and rice, *Oryza sativa*) crops at 0.04, 0.08, 0.16, 0.32, 0.64, and 1.28 lb a.i./A and dicot (cabbage, *Brassicacea oleracea*; cotton, *Gossypium hirsutum;* cucumber, *Cucumis sativus*; radish, *Raphanus sativus*; soybean, *Glycine max*; and sunflower, *Helianthus annuus*) crops at 0.02, 0.04, 0.08, 0.16, 0.32, 0.64 lb a.i./A was studied for 21 days.

Tebuthiuron did not interfere with seed emergence of any of the species tested. One week after emergence, radish was determined to be extremely sensitive to tebuthiuron at 0.08 lb a.i./A. After three weeks, radish, cucumber, cabbage, and wheat were severely injured. At the high rate tested, seedlings of these species were killed. Corn, rice, cotton, and sunflower were intermediate in susceptibility and were injured 50% or more at the highest test level tested. The study author determined a NOAEC of 0.02 lb a.i./A for dicots and 0.04 lb a.i./A for monocots three weeks after treatment. Early injury symptoms were chlorosis and stunting of plants followed by burning of leaves and eventual plant death of some species at the highest test level. All species were reduced in height as the application rate was increased. Cucumber, radish, cabbage, and wheat were reduced the most.

The most sensitive monocot species was wheat based on fresh weight, with NOAEC and EC_{25} values of 0.04 and 0.07 lb a.i./A, respectively. The most sensitive dicot species was cabbage based on fresh weight, with NOAEC and EC_{25} values of 0.02 and 0.03 lb a.i./A, respectively.

This toxicity study is scientifically sound and satisfies the guideline requirement for a Tier II seedling emergence toxicity study. This study is classified as Acceptable.

<u>MRID 41066902</u>

The effect of the technical grade of tebuthiuron on the seed germination of monocot (corn, *Zea mays*; wheat, *Triticum aestivum*; sorghum, *Sorghum bicolor*; and rice, *Oryza sativa*) crops and dicot (cabbage, *Brassicacea oleracea*; cotton, *Gossypium hirsutum;* cucumber, *Cucumis sativus*; radish, *Raphanus sativus*; soybean, *Glycine max*; and sunflower, *Helianthus annuus*) crops at the maximum application rate of 6.0 lb a.i./A was studied for 5 days.

Analysis of the data was by visual observation. No significant differences were noted between treated and control groups. Corn, sorghum, wheat, rice, soybean, cucumber, sunflower, and radish seeds were not affected, while cotton and cabbage germination was 2.8% and 3.8% less than the controls. The germination percentage for corn, sorghum, wheat, rice, soybean, cucumber, sunflower, cabbage, cotton, and radish was 100%, 95%, 99%, 76%, 88%, 99%, 96%, 73%, 97%, and 100%, respectively.

This study is no longer required by EPA; however, provides useful information on tebuthiuron to terrestrial plants.

<u>MRID 48722703</u>

The effect of **Spike 20P (AI: Tebuthiuron)** on the seedling emergence of monocot (onion, *Allium cepa*; corn, *Zea mays*; oat, *Avena sativa*; and ryegrass, *Lolium perenne*) and dicot (carrot, *Daucus carota*; cucumber, *Cucumis sativus*; cabbage, *Brassicacea oleracea*; soybean, *Glycine max*; sugarbeet, *Beta vulgaris*; and tomato, *Lycopersicon esculentum*) crops was studied at the following nominal concentrations:

<u>Sugarbeet, tomato, and cabbage:</u>

0 (negative control), 0.0020, 0.0039, 0.0078, 0.016, 0.031, 0.062, 0.12, 0.25, 0.50, and 1.0 lb a.i./A

<u>Soybean:</u>

0 (negative control), 0.0020, 0.0039, 0.0078, 0.016, 0.031, 0.062, 0.12, 0.25, 0.50, 1.0, and 2.0 lb a.i./A

<u>Onion, ryegrass, oat, carrot, and cucumber:</u>

0 (negative control), 0.0078, 0.016, 0.031, 0.062, 0.12, 0.25, 0.50, 1.0, 2.0, and 4.0 lb a.i./A

<u>Corn:</u>

0 (negative control), 0.062, 0.12, 0.25, 0.50, 1.0, 2.0, and 4.0 lb a.i./A.

The growth medium used in the seedling emergence test was natural soil mixed with silica sand (loam, pH 6.5, organic carbon 1.0%). On day 21 the surviving plants per pot were recorded and cut at soil level for measuring the plant height and fresh weight.

Fresh weight and height were significantly affected in every species tested. Survival (% survived of planted) was significantly affected in all species except soybean. Emergence was only significantly affected in cabbage and tomato. The % inhibition in seedling emergence in the treated species as compared to the control ranged from 3 to 52%. The most sensitive monocot species, based on fresh weight, in the seedling emergence test was ryegrass with an EC_{25} of 0.27 lb a.i./A and a NOAEC of 0.25 lb a.i./A. The most sensitive dicot species, based on fresh weight, was carrot with an EC_{25} of 0.018 lb a.i./A and a NOAEC of 0.031 lb a.i./A.

However, the study author reported analytical recoveries of the test material from nominal 1.0, 2.0, and 4.0 lb a.i./A test levels yielded pre-application recoveries ranging from 37 to 76% of the nominal concentrations. At the first post-application, recoveries ranged from 63 to 66% of the nominal concentrations. At the second post-application, recoveries ranged from 39 to 50% of the nominal concentrations. The lower test concentrations were not verified. The study author averaged all of the application data and averaged all the percent recoveries to obtain a single recovery value of 56% of nominal. If the reviewer's results are adjusted for the 56% average recoveries, the most sensitive monocot species was ryegrass based on fresh weight, with NOAEC and EC_{25} values of 0.14 and 0.15 lb a.i./A, respectively. The most sensitive dicot species was carrot based on fresh weight, with NOAEC and EC_{25} values of 0.017 and 0.010 lb a.i./A, respectively.

There were compound related phytotoxic effects observed in every species tested, with a dose-response relationship expressed in the upper 4-5 test levels. Based on the phytotoxicity rating system used by the study author (0 = no injury, 100 = complete mortality), soybean and corn had maximum effects of 63 and 70. All other species tested except carrot and cucumber had maximum ratings ranging from 85 to 97. Carrot and cucumber experienced complete mortality, with a rating of 100.

This toxicity study is scientifically sound but does not satisfy the guideline requirement for a Tier II seedling emergence toxicity study. This study is classified as Supplemental.

OCSPP 850.4150 – Vegetative Vigor Toxicity Test

MRID 48722704

The effect of **Spike 20P (AI: Tebuthiuron)** on the vegetative vigor of monocot (onion, *Allium cepa*; corn, *Zea mays*; oat, *Avena sativa*; and ryegrass, *Lolium perenne*) and dicot (carrot, *Daucus carota*; cucumber, *Cucumis sativus*; cabbage, *Brassicacea oleracea*; soybean, *Glycine max*; sugarbeet, *Beta vulgaris*; and tomato, *Lycopersicon esculentum*) crops was studied at the following nominal concentrations up to 4.0 lb a.i./A:

Sugarbeet, tomato, and cabbage:
0 (negative control), 0.0020, 0.0039, 0.0078, 0.016, 0.031, 0.062, 0.12, 0.25, 0.50, and 1.0 lb a.i./A
Soybean:
0 (negative control), 0.0020, 0.0039, 0.0078, 0.016, 0.031, 0.062, 0.12, 0.25, 0.50, 1.0, and 2.0 lb a.i./A
Onion, ryegrass, oat, carrot, and cucumber:
0 (negative control), 0.0078, 0.016, 0.031, 0.062, 0.12, 0.25, 0.50, 1.0, 2.0, and 4.0 lb a.i./A

Corn:
0 (negative control), 0.12, 0.25, 0.50, 1.0, 2.0, and 4.0 lb a.i./A.

The growth medium used in the vegetative vigor test was natural soil mixed with silica sand (loam, pH 6.5, organic carbon 1.0%). On day 21 the surviving plants per pot were recorded and cut at soil level for measuring the plant height and fresh weight.

In the vegetative vigor test, the plant fresh weight and shoot length were significantly affected by the test material. Survival was significantly affected in onion, oat, carrot, cucumber, and sugarbeet.

The most sensitive monocot species, based on fresh weight, in the vegetative vigor test was ryegrass with an EC_{25} of 0.30 lb a.i./A and a NOAEC of 0.12 lb a.i./A. The most sensitive dicot species, based on fresh weight, was sugarbeet with an EC_{25} of 0.16 lb a.i./A and a NOAEC of 0.062 lb a.i./A.

However, the study author reported analytical recoveries of the test material in the nominal 1.0, 2.0, and 4.0 lb a.i./A test levels yielded pre-application recoveries ranging from 50 to 84% of the nominal concentrations for all species except cucumber, and 38 to 71% of nominal for cucumber. At post-application, recoveries ranged from 55 to 84% (all species except cucumber), and from 44 to 88% (cucumber) of the nominal concentrations. The lower test concentrations were not verified. The study author averaged all of the application data and averaged all the percent recoveries to obtain a single recovery value of 61% of nominal. If the reviewer's results are adjusted for the 61% average recoveries, the most sensitive monocot species was ryegrass based on fresh weight, with NOAEC and EC_{25} values of 0.07 and 0.18 lb a.i./A, respectively. The most sensitive dicot species was sugarbeet based on fresh weight, with NOAEC and EC_{25} values of 0.04 and 0.10 lb a.i./A, respectively.

There were compound related phytotoxic effects observed in every species tested, with a dose-response relationship expressed in the upper 3-5 test levels. Based on the phytotoxicity rating system used by the study author (0 = no injury, 100 = complete mortality), corn and soybean had maximum effects of 36 and 46, respectively. Ryegrass, tomato, sugarbeet, and cabbage had maximum ratings ranging from 54 to 76. Onion, oat, carrot, and cucumber had maximum ratings ranging from 86 to 98.

This toxicity study is scientifically sound but does not satisfy the guideline requirement for a Tier II vegetative vigor toxicity study. This study is classified as Supplemental.

OCSPP 850.4400 – Aquatic Plant Toxicity Test Using Lemna spp.

MRID 41080404
In a 14-day acute toxicity study, freshwater aquatic vascular plants, duckweed (*Lemna gibba*), were exposed to tebuthiuron mean-measured concentrations of <0.005 (<LOD), 0.005, 0.0096, 0.049, 0.091, 0.19, 0.38, and 0.78 mg a.i./L.

The percent inhibition of frond density after 7 and 14 days ranged from 15% to 86% and -6% (stimulation) to 98%, respectively. The percent inhibition of yield at 7 and 14 days, calculated from frond density, ranged from 16% to 90% and -6% to 100%, respectively. The percent inhibition of growth rate at 7 and 14 days, calculated from frond density, ranged from 6% to 61% and -1% to 99%, respectively. The percent inhibition of frond dry weight (biomass) after 14 days ranged from -21% to 98%. The percent inhibition of yield after 14 days, calculated from frond dry weight, ranged from -22% to 100%. The percent inhibition of growth rate after 14 days, calculated from frond dry weight, ranged from -5% to 100%. The 7-day EC_{50} reviewer-calculated for yield and growth rate of frond density was 0.192 and 0.495 mg a.i./L, respectively. The 14-day EC_{50} reviewer-calculated for yield and growth rate of frond dry weight was 0.126 and 0.205 mg a.i./L, respectively. Yield in frond dry weight was the most sensitive endpoint, its corresponding NOAEC was 0.091 mg a.i./L due to significant differences between the negative control and the three highest test concentrations.

This toxicity study is scientifically sound and does not fulfill the guideline requirement for a Tier II aquatic vascular plant toxicity study with duckweed, *Lemna gibba*. This study is classified as supplemental.

OCSPP 850.4500 – Algal Toxicity Test

MRID 00138697

In a 14-day toxicity study, freshwater green alga, *Selenastrum capricornutum*, were exposed to tebuthiuron nominal concentrations of 0 (negative control), 5, 10, 15, 20, 40, 80, 160, and 320 µg/L under static conditions. The mean-measured test concentrations were 0 (control; LOD <0.5 µg/L), 5, 10, 13, 16, 33, 79, 168, and 338 µg a.i./L. After 5 days, the percent inhibition in biomass relative to the control ranged from 0% to 83%. The 5-day EC_{50} and NOAEC was 50 and 13 µg a.i./L, respectively.

This toxicity study is scientifically sound and does not fulfill the guideline requirement for a Tier II algal toxicity study with freshwater green algae, *Selenastrum capricornutum*. This study is classified as supplemental.

MRID 41080402

In a 7-day toxicity study, cultures of the marine diatom, *Skeletonema costatum*, were exposed to tebuthiuron nominal concentrations of 0 (negative control), 0.002, 0.01, 0.02, 0.04, 0.08, 0.16, and 0.32 mg a.i./L under static conditions. Mean-measured concentrations were 0.0018, 0.0092, 0.018, 0.038, 0.076, 0.16, and 0.3 mg a.i./L.

After 96-hr and 168-hr, the percent inhibition in yield, calculated from cell density, relative to the control ranged from 38% to 105% and -36% to >100%, respectively. The percent inhibition in AUC (area under the curve), calculated from cell density, relative to the control ranged from -4% to 82% and -21% to 98% at these respectively times. The percent inhibition in growth rate, calculated from cell density, relative to the control at 96-hr and 168-hr ranged from 15% to >100% and -9% to >100%, respectively. The 96-hr EC_{50} for yield, AUC and growth rate was 0.05 mg a.i./L, 0.06 mg a.i./L, and not calculable, respectively. With yield as the most sensitive endpoint, its corresponding NOAEC was 0.038 mg a.i./L based upon significant reductions in yield detected between the control and the three highest test concentrations of the seven test concentrations tested.

This toxicity study is scientifically sound but does not satisfy EPA guideline requirements for a Tier II aquatic nonvascular plant toxicity study with the marine diatom, *Skeletonema costatum*. This toxicity study is classified as supplemental.

MRID 41080403

In a 7-day toxicity study, cultures of the freshwater diatom, *Navicula pelliculosa*, were exposed to tebuthiuron nominal concentrations of 0 (negative control), 0.005, 0.01, 0.05, 0.1, 0.2, 0.4, and 0.8 mg a.i./L. Mean-measured concentrations were <0.005 (<LOD), 0.0012, 0.011, 0.056, 0.11, 0.22, 0.46, and 0.89 mg a.i./L, 82-107% of nominal concentrations.

After 96-hr and 168-hr, the reviewer-calculated percent inhibition in yield based on cell density relative to the control ranged from 11% to 100% and -17% to 100%, respectively. The percent inhibition in area under the growth curve, calculated from cell density, relative to the control ranged from -5% to 109% at 96 hours and -19% to 98% at 168 hours. The percent inhibition in growth rate relative to the control at 96 and 168 hours ranged from 4% to 100% and -3% to 112%, respectively. The reviewer-calculated 96-hour EC_{50} for yield, area under the growth curve, and growth rate was 0.09, 0.1, and 0.18 mg a.i./L. Significant reductions in yield, the most sensitive endpoint, were detected between the control and the four highest test concentrations; as of a result, the corresponding NOAEC was 0.056 mg a.i./L.

This toxicity study is scientifically sound but does not fulfill EPA guideline requirements for a Tier II aquatic nonvascular plant toxicity study with the freshwater diatom, *Navicula pelliculosa*. This toxicity study is classified as supplemental.

OCSPP 850.4550 – Cyanobacteria (Anabaena flos-aquae) Toxicity Test

MRID 41080401

In a 7-day toxicity study, cultures of the freshwater blue-green algae, *Anabaena flos-aquae*, were exposed to tebuthiuron nominal concentrations of 0 (negative control), 0.31, 0.62, 1.25, 2.5, 5, and 10 mg a.i./L. Mean-measured concentrations were <0.012 (<LOD), 0.31, 0.62, 1.32, 2.62, 5.49, and 11.05 mg a.i./L, 98-105% of nominal concentrations.

At 96-hr and 168-hr, the reviewer-calculated percent inhibition in yield based on cell density relative to the control ranged from 13% to 88% and -2% (growth) to 88%, respectively. The percent inhibition in area under the growth curve based on cell density relative to the control ranged from 10% to 87% and 7% to 87% at these respectively times. The percent inhibition in growth rate based on cell density relative to the control at 96-hr and 168-hr ranged from 3% to 43% and -0.2% (growth) to 39%, respectively. The study author based it conclusions upon test termination that lasted 168 hours; however, OSCPP guideline 850.4500 prefers 96 hours toxicity endpoints. The reviewer-calculated 96-hour EC_{50} for yield, area under the growth curve, and growth rate was 0.81, 1.09, and >11.05 mg a.i./L, respectively. Significant reductions in yield, AUC, and growth rate were detected between the control and all test concentrations, its NOAEC could not be established. With yield as the most sensitive endpoint, its corresponding EC_{05} was 0.03 mg a.i./L.

This toxicity study is scientifically sound however does not fulfill EPA guideline requirements for a Tier II aquatic nonvascular plant toxicity study with the freshwater blue-green algae, *Anabeana flos-aquae*. This toxicity study is classified as Supplemental.